Appendix B: Comment Index, Written Comments with Attachments, Public Hearing Transcript, and Responses to Comments for Original Proposed Rule

Name	Representing	pg #
Adams Tamara	Private Citizen	253
Aegerter Bob	Private Citizen	296
Al-Mondhiry, Rend	Consumer Healthcare Products Association	333
Anderson Brooks	Private Citizen	291
Angell Bryony	Private Citizen	278
Antolin Trudy	Private Citizen	306
Aragon, Sophia	Washington State Nurses Association	PH3
Bangs Leigh	Private Citizen	276
Banse Liz	Private Citizen	252
Barbara Losey	Alkylphenols & Ethoxylates Research Council	30
Benefield Earlene	Private Citizen	301
Bergholm Yvonne	Private Citizen	304
Berry, Leslie	American Chemistry Council Ketones Panel	13
Berry, Leslie	American Chemistry Council Oxo Process Panel	19
Biery Boni	Private Citizen	297
Blakey Allen	Vinyl Institute	245
Brady Patricia	Private Citizen	264
Brough, Steve	WashPIRG	PH3
Bryant Bill	Private Citizen	312
Burrows Beth	Private Citizen	331
Busch, Jon	American Chemistry Council Phenol Panel	94
Callahan Cindy	Private Citizen	313
Cappio Gretchen	Private Citizen	285
Carlsen Debbie	Private Citizen	318
Cates, Edward	Family Physician	PH4
Coates-Robertson Jamie	Private Citizen	305
Colangelo Annapoorne	Private Citizen	309
Cooney Glen	Consumer Electronics Retailers Coalition	396
Cornelsen Christy	Private Citizen	320
Cupiccia Jami	Private Citizen	266
Davis Galen	Private Citizen	299
Doty Beverly	Private Citizen	298
Duvall, Amy	American Chemistry Council	62
Dyer, Anna for Allen, Jennifer	Planned Parenthood	PH9
Dyer, Garrison	Science Teacher	PH9
Elliott Ingrid	Private Citizen	319
Ellis Scott	Private Citizen	330
Erwin Michelle	Private Citizen	307
Fleece Jamie	Silicones Environmental Health and Safety Council	411
Foley Sarah	Private Citizen	323
G Donahue	Private Citizen	1
Galvin, Dave	King Co. Depart. Natural Resources and Parks	58
Garst Sam	Private Citizen	280
Ginsburg Joe	Private Citizen	310
Grady, Richard	Private Citizen	440
Guay, Chris	Procter and Gamble Co.	444 & PH1
Guichard, Maryanne	Washington Department of Health	336
Guse Samantha	Private Citizen	302
Guth Dorothy	Private Citizen	292
Haberly Brian	Private Citizen	308
Hackman, Andy	Toy Industry Association	422 & PH5
Hamann Patricia	Private Citizen	294
Hamer Suzanne	Private Citizen	332
Harris James	Private Citizen	328
Hart, Laura	Washington Physicians for Social Responsibility	PH8
Havens Lorena	Private Citizen	295
Head Thomas	Wal Mart	437
Hentges, Steve	American Chemistry Council Polycarbonate/BPA Global Group	68
Hinton Colleen	Private Citizen	288
Hirsch, Evan	Family Physician	PH2
Hoggard Laurie	Private Citizen	251
Holman Cherie	Private Citizen	316

Hostetter Suzanne	Private Citizen	**265**
Jancoski Loretta	Private Citizen	**286**
Jaques Helga	Private Citizen	**281**
Johnson Mark	Washington Retail Association	**233**
Kelly Angela	Private Citizen	**259**
Krell Mieko	Private Citizen	**293**
Kuehl Lillian	Private Citizen	**275**
Lamar Steve	American Apparel and Footware Association	**2**
Laz Thom	Private Citizen	**255**
Lewandowski Tom	Gradient	**241 & PH6**
Logan Kerry	Private Citizen	**324**
Lott Alan	Private Citizen	**272**
Maia Jack	Grocery Manufacturers Association	**380**
Martin Deborah	Private Citizen	**267**
Mason, Ann	American Chemistry Council Formaldehyde Panel	**9**
Meyer Mickie	Private Citizen	**325**
Mikalson Claire	Private Citizen	**303**
Mikkelsen Michelle	Private Citizen	**248**
Mitts Jared	Private Citizen	**317**
Moore Robert	Private Citizen	**311**
Morris Dan	Private Citizen	**300**
Mullen Kay	Private Citizen	**287**
Myers Tom	Personal Care Products Council	**430**
Nelson Grant	Association of Washington Business	**340**
Petersen Deborah	Private Citizen	**277**
PetersThom	Private Citizen	**322**
Power Kristin	Consumer Specialty Products Association	**407**
Price Karen	Private Citizen	**261**
Pringle Bruce	Private Citizen	**327**
Queary Bart	Private Citizen	**249**
Rickert, Allen	Top Ten Toys	**441**
Rieger Reingard	Private Citizen	**269**
Rivero Ana	Private Citizen	**254**
Roberts Cal	Private Citizen	**263**
Rolland Janna	Private Citizen	**268**
Rolland Seth	Private Citizen	**284**
Romito Rick	Private Citizen	**262**
Rosewarne Heather	Private Citizen	**273**
Rothstein, Zachary	Fashion Jewelry and Accessories Trade Association	**345**
Sammons Valerie	Private Citizen	**315**
Schreder Erika	Washington Toxics Coalition	**392 & PH6**
Silk Road	Silk Road	**400**
Slemons Lia	Private Citizen	**271**
Snyder Jack	Styrene Information and Research Center	**87**
Solomon Laurie	Private Citizen	**256**
St. Martin Darlene	Private Citizen	**329**
Struyk, William [JJCUS]	Johnson & Johnson	**237**
Thompson Laurie	Private Citizen	**279**
Truskoff Lou & Joan	Private Citizen	**258**
Utz Pam	GAP, NIKE, H&M, LS&C	**403**
Villines Monica	Private Citizen	**283**
Vos Johari	Private Citizen	**321**
Wahosi Mare	Private Citizen	**314**
Weathers Corey	Private Citizen	**260**
Wilhelm Joellen	Private Citizen	**282**
Zimmerly Elizabeth	Private Citizen	**289**

From: G Donahue
To: Williams, John (ECY);
Subject: A few thoughts regarding the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 3:40:31 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

G Donahue
18012 14th Pl W
Lynnwood, WA 98037

From: Steve Lamar
To: Williams, John (ECY);
cc: Steve Lamar; Gregory Yahr; Rebecca Mond; Nate Herman; Scott Elmore;
Subject: AAFA Comments on Washington State CPSA Draft Reporting Regulations
Date: Friday, January 07, 2011 12:03:01 PM
Attachments: washingtonstatecpsareportingrulecomments110107.pdf

---

Hi John –

Happy New Year.

Hope you are doing well.

Please find attached AAFA's comments for the Washington State CPSA reporting regulation.

I look forward to working with you on the development and implementation of this rule moving forward.

Thanks

Steve

Steve Lamar
AAFA
1601 N. Kent Street, 12th Floor
Arlington, VA 22209
Direct: 703-797-9041
Cell: 571-332-6449
Email: slamar@apparelandfootwear.org

January 7, 2011

John R. Williams Jr.
Washington State Department of Ecology
PO Box 47600
Olympia WA 98504-7600

Via e-mail: john.williams@ecy.wa.gov

REF: Rule Proposal Notice Chapter 173-334 WAC, Children's Safe Products Reporting Rule

Dear Mr. Williams:

On behalf of the American Apparel & Footwear Association (AAFA) – the national trade association for the apparel and footwear industries, and their suppliers – I am writing to provide information about AAFA and to comment on the draft regulations for the Children's Safe Products Reporting Rule (173-334 WAC).

AAFA's members include numerous companies that design, manufacture, transport, distribute, and sell apparel and footwear in and through Washington. Collectively, they employ thousands of people throughout Washington. AAFA has about 400 member companies who own, produce for, or market more than 700 brands of clothing, footwear, and other fashion products. Nearly all stakeholders in the industry supply chain are represented in our membership, including large, medium, small, and micro businesses; retailers of all sizes; designers; manufacturers; importers; wholesalers; private label; brand owners; and suppliers of inputs and services. We represent the greatest cross-section of this industry.

Environmental and product safety work has been a growing and sustained area of the AAFA agenda for some time. For example, our Environmental Committee has grown tremendously over the past decade and now numbers about 150 professionals from throughout the industry. Through this Committee, AAFA has developed an array of environmental tools, including a best practices list and an industry restricted substances list (RSL) that is freely available at www.apparelandfootwear.org. Our Product Safety Council, which specifically addresses product safety issues, is one of our more active Committees. It now boasts over 400 members. AAFA uses the Product Safety Council to distribute information, develop industry positions, create best practices, and keep members up to date on the ever changing product safety landscape.

Educating the apparel and footwear industry supply chain on product safety compliance initiatives has been a top priority for AAFA for decades. Furthermore, over the past two years, AAFA and various international partners have conducted nearly a hundred webinars, briefings, conferences and trainings, throughout the United States and on four continents on restricted substances, chemical management, and other product safety topics. Two months ago we held

1601 North Kent Street, Suite 1200, Arlington, VA 22209 www.apparelandfootwear.org p (703) 524-1864 (800) 520-2262 f (703) 522-6741

our first seminar on this important topic in Vietnam to educate our members' suppliers – our 7th such program in Asia in the past three years. In a few months we return to Asia to conduct a 6th restricted substance seminar in China.

In addition, we have partnered with a number of other organizations doing ground-breaking work on sustainable initiatives. We recently endorsed the Eco Index, which has been developed by the Outdoor Industry Association (OIA), to provide apparel and footwear companies (among others) with a common approach to measuring sustainability at the product and facility level. We are also encouraging our members to explore other initiatives, such as those promoted by Business for Social Responsibility's (BSR) Apparel, Mills and Sundries Working Group and the National Resources Defense Council (NRDC) Clean By Design.

As a general point, we wish to commend you and your agency for your extensive outreach to interested stakeholders and for conducting a rule-making that had provided many opportunities to interact with you and examine the regulations as they have evolved. We are particularly pleased that AAFA, and several of its members, were able to participate or track the development of the rule through a pilot process earlier this year. In addition, we thank you again for presenting an update on the rule to our Environmental Committee during its January 2010 meeting. Your approach and this regulatory philosophy should be a model for other state and federal agencies.

It is with this in mind that we are offering the following comments.

Recap

As we understand it, the rule envisions the annual reporting of chemicals of high concern to children (CHCC) that are present in children's products, or in components of children's products, that are manufactured for sale in Washington State[1]. Children are defined as individuals under the age of 12 (in other words individuals who are 11 years or younger).[2] Manufacturers are defined as a person or entity that produces a children's product, any importer that assumes ownership of a children's product, and any domestic distributor of a children's product.[3]

While CHCC reporting will occur on an annual basis, initial reporting will occur according to a phase-in schedule that assigns different timelines to different tiers of products and sizes of manufacturers. Our initial read of that table[4] is that most clothing and footwear will fall under Tier 2. Clothing and footwear intended for children aged 3 and under will fall under Tier 1. Many accessories, such as backpacks or purses, would fall under Tier 3. We note, however, that many components in children's clothing, footwear, and accessories are in fact inaccessible, which would classify them in Tier 4 (case-by-case reporting).

[1] See Chapter 173-334-110 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). p. 6.
[2] See Chapter 173-334-040 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). p. 2.
[3] See Chapter 173-334-100 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). p. 5.
[4] See Chapter 173-334-120 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). p. 7.

According to the draft rule, reporting is the responsibility of the manufacturer. The rule further sets out information that is required to be contained in each annual report. Reporting can be done directly by the manufacturer or by a trade association representing a group of manufacturers, such as AAFA. In the case of reporting by the trade association, each manufacturer covered by the reporting must be identified.[5]

The rule sets out an initial list of CHCCs.[6] The Department will periodically review the list of CHCCs and may, subject to such review or following a petition, add or subtract substances from the list of CHCCs.[7]

Finally, the rule further clarifies that "reporting the presence of a CHCC does not establish that the product is harmful to human health."[8]

Comments, Questions, and Concerns

The rule appears to provide considerable flexibility to manufacturers as they carry out their reporting obligation. We believe this is critical to the success of the rule since manufacturers – in other words those parties responsible for designing the product in the first place – are the most knowledgeable about their product and the substances they may or may not contain. For example, a product component is defined as a "uniquely identifiable piece, substrate, or coating."[9] Likewise, inaccessibility is clarified as "inaccessible internal components for all children's products."[10] Implicit in that definition is the concept that it is up to the manufacturer to make the assessment over what is uniquely identifiable or what is inaccessible. Among other things this approach avoids, to a large degree, a one-size-fits-all standard that is usually inconsistent with effective product safety management across a wide range of products and consumers. As the Department continues to move forward on implementation, including continued rule making, we would urge that this principle be closely followed.

Similarly in defining the concept of product category, the Department relies upon industry accepted protocols – the GS1 Global Product Classification (GPC) standards – to classify products for children's products (including those for children aged 3 and under). Relying upon commonly accepted protocols in this manner helps companies align this new reporting burden with their existing supply chain communications and will help ensure that companies are not forced to "reinvent the wheel."

On that note, although the draft regulation has two age related requirements (3 and under; 11 and under) we note that, in our industry, products are rarely defined by the age. Our industry most often communicates with sizes. It is our expectation that the Department will defer to

[5] See Chapter 173-334-090 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). p. 4.
[6] See Chapter 173-334-140 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). pp. 9-11.
[7] See Chapter 173-334-060 - 080 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). pp 3-4.
[8] See Chapter 173-334-010 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). p. 1.
[9] See Chapter 173-334-040 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). p. 2.
[10] See Chapter 173-334-120 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). p. 8.

manufacturers to best identify the sizes that correspond to the specific age ranges the Department has articulated.

We welcome that there Department envisions a regular review regarding changes to the CHCC list. The Department should build on its current listserv of interested stakeholders – including those individuals involved in the development of regulations and those who report under the rule – so they can be kept informed of any such changes. We trust the Department will also ensure that there is adequate opportunity for comment of any proposed changes and ample phase-in of reporting obligations of any new chemicals that are added. We would suggest that any new chemicals follow a phase-in schedule similar to the one outlined for initial reporting.[11]

We are particularly pleased that the rule permits manufacturers to report through trade associations. This makes sense from several perspectives, including the provision of an additional filter for confidential business information (CBI) and the opportunity to consolidate information across an industry. We are also pleased that the Department has outlined an easy and self-executing method for companies to declare information to be CBI. Companies are in the best position to determine what information contains trade secrets.

With respect to trade association reporting, we are exploring how AAFA can best serve its members' needs in this area. One question we have is which timeline AAFA would follow if it aggregates reporting for manufacturers of different sizes. For example, if we intend to report for Tier 2 products for 6 manufacturers representing each classification size, would our initial reporting occur in 18 months (largest class) or 72 months (tiny class) or some combination? Our initial reading is that we would report our largest manufacturers at 18 months, and then phase in smaller manufacturers at the next due date. If that is the case, our reporting would be out of sync since some of the gaps between manufacturer sizes are 6 months and some are 12 months. We would encourage the Department to clarify the application of the timeline for associations and suggest that all timelines for initial phase-ins be pegged at 12 month intervals.

We strongly agree with the statement that reporting the presence of a CHCC does not indicate a health or safety concern. We would seek a further clarification that such reporting similarly does not indicate a lack of compliance of a product safety standard. Clear statements such as these are needed to help make sure the public understands the health and safety impact, and that businesses understand the compliance liabilities, of the information that will be reported subject to this rule.

Notwithstanding the above, we remain concerned over how the information in this reporting rule will be interpreted and used. It is critically important that information on the presence of substances be fully understood in light of the risks and exposures pathways those substances may or may not present.[12] We recommend that the Department use the information reported for its own purposes and refrain from disclosing it to the general public since such disclosures often fuel public misperceptions and confusion and contribute to public "fatigue" over legitimate product safety concerns.

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[11] See Chapter 173-334-120 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf). p. 6-7.

[12] Cobalt for example is listed on the CHCC yet is also a chemical widely viewed as an essential ingredient for human life. Among other things it is a key constituent of vitamin B-12.

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Another concern, that we have brought your attention previously and which is commonly cited by members, deals with the proliferation of state-based chemical reporting programs. We believe the Department is also sensitive to this issue and in fact commend you for recognizing federal preemption of parts of the Children's Safe Product Act (CSPA) by the Consumer Product Safety Improvement Act of 2008 (CPSIA). We ask that, as you interact with your colleagues and counterparts in other state and federal agencies, you continue to work toward ways to reduce the kinds and diversity of reporting requirements. Product safety does not know state boundaries.

On that note, and since the regulation is a reporting requirement and not a safety standard, we would encourage the Department to clarify that the reporting requirement does not apply to manufacturers who do not envision the consumption of their product in Washington State. While, the vast majority of our members sell their products nationwide, several members sell to local markets that do not include Washington State. Whether through brick and mortar or online, these companies cannot be held responsible to incur a reporting obligation if a consumer buys a product and then transports it to Washington State without their knowledge.

Finally, we remain deeply concerned that the regulation suggests that companies may have to test for the presence of every CHCC even if there is no intention or expectation that that substance is included. For example, BPA is identified as a CHCC but there is no expectation that this substance would be included in footwear or apparel since it is more commonly associated with hard plastic containers, like water bottles. Would a company have to test for BPA to establish its knowledge base that it doesn't exist so that it can report accordingly? We believe the Department should clarify that such testing and reporting does not need to occur. To further prevent such a scenario, we would make several recommendations to the reporting methodologies.

First, we would encourage the Department to entertain alternative reporting methodologies that would further lessen the burden on companies while providing information about chemicals of concern. One approach that several of our members have suggested, and which we believe was separately communicated to you, would permit companies to report through their restricted substance lists (RSLs), through which many companies implement their chemical management program. In this approach, we would envision companies reporting that they make products in conformity with a particular RSL, and subsequently report that RSL.[13]

Second, we recommend the Department consider revising the reporting limits to a common level – such as 1000ppm, which is the amount set for reporting under REACH for Substances of Very High Concern (SVHC).[14] This would have the advantage of harmonizing the Washington state rules with an existing regulation while creating a *de minimis* level to focus reporting requirements on those CHCCs in larger concentrations in products. This would also ease paperwork burdens on the reporting community while giving stakeholders a more digestible dataset of information than the current list of five reporting categories (of which the 1000ppm is the middle level).

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[13] AAFA maintains an industry wide RSL that is updated every six month and freely available at: http://www.apparelandfootwear.org/Resources/RestrictedSubstances.asp

[14] See for example: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_obligations_en.asp

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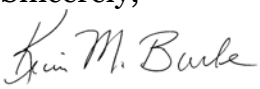
We look forward to continued dialogue with the Department on this regulation. We are particularly interested in any thoughts the Department has on how the "case by case" reporting will occur.

Conclusion

We are best served when we have a product safety regulatory system that ensures that only safe and compliant products be designed, produced, marketed, and sold – whether in Washington State or throughout the world. At AAFA, and throughout the industry, we take our product safety education and advocacy efforts seriously. We view this obligation as key to the success of the industry, not only because such an approach is the right thing to do, but because we are also consumers, parents, and grandparents ourselves. We believe very strongly that we should only wear safe and compliant clothes, shoes, and other products.

Thank you for providing us this opportunity to comment. We would welcome an opportunity to discuss these ideas further. In the meantime, please feel free to contact Greg Yahr (gyahr@apparelandfootwear.org) or Steve Lamar (slamar@apparelandfootwear.org) on my staff should you require additional information.

Sincerely,



Kevin M. Burke
President and CEO

From: Mason, Ann
To: Williams, John (ECY);
cc: Duvall, Amy;
Subject: ACC formaldehyde comments on proposed WAC 173-334
Date: Friday, January 07, 2011 2:39:34 PM
Attachments: 2011_jan7_FA comments to WA childrens products rule.pdf

---

Dear Mr. Williams,

The Formaldehyde Panel of the American Chemistry Council (ACC) appreciates the opportunity to comment on the Department of Ecology's (DOE) WAC 173-334, proposed regulations to implement the Children's Safe Products Act. The safety of children's products is of the utmost importance, and addressing the potential risks faced by children from possible exposure to chemicals is an important objective of the proposed regulations. Although ACC supports several concepts in the proposed regulations, there are several provisions that cause concern. These comments supplement those submitted by Michael Walls on December 17, 2010, which are incorporated by reference.

Our comments (attached) are focused on the minimum reporting threshold, which we assert is not appropriate for formaldehyde.

I look forward to having an opportunity to further conversations with you and to supplement these comments as appropriate.

Sincerely,

Ann M. Mason
Senior Director
American Chemistry Council
700 2nd St NE
Washington, DC 20002
202.249.6704
ann_mason@americanchemistry.com

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January 7, 2011

SENT VIA ELECTRONIC MAIL

Mr. John R. Williams
Washington State Department of Ecology
W2R HQ
P.O. Box 47775
Olympia, WA 98540-7775
jowi461@ecy.wa.gov

RE: Formaldehyde Panel of American Chemistry Council Comments on Proposed WAC 173-334

Dear Mr. Williams

The Formaldehyde Panel of the American Chemistry Council (ACC) appreciates the opportunity to comment on the Department of Ecology's (DOE) WAC 173-334, proposed regulations to implement the Children's Safe Products Act. The safety of children's products is of the utmost importance, and addressing the potential risks faced by children from possible exposure to chemicals is an important objective of the proposed regulations. Although ACC supports several concepts in the proposed regulations, there are several provisions that cause concern. These comments supplement those submitted by Michael Walls on December 17, 2010, which are incorporated by reference.

The 40 ppm Minimum Reporting Threshold Is Not Appropriate for Formaldehyde

WAC 173-334-090 establishes a minimum reporting threshold of 40 ppm (0.004%). As discussed in the December 17, 2010 comments, ACC recommends a reporting threshold of 1,000 ppm (0.1%) for all potential chemicals of concern. The 40 ppm threshold is particularly inappropriate for formaldehyde because it does not take into account how formaldehyde is measured and analyzed using internationally-accepted standards for skin contact in clothing meant for children 3 years and older and adults. Formaldehyde is widely used in textile processing, *e.g.*, as active ingredient in fixing agents (pigment printing, coating, finishing), cross-linking agents (non-iron, wrinkle-free finishing for cotton), and as a preservative, and the toxicological properties of formaldehyde are well known.

Today, most of the tests with clothing containing formaldehyde are done according to the international standard ISO 14184-1[1] and done in such a manner (*i.e.*, using extraction with water)

[1] Available at http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=23871.

so as to simulate perspiration. (As an example of testing differentiation, chipboard is tested in a gas chamber to simulate behavior as construction material.) International authorities[2] have made clear that when a textile product comes into direct contact with the skin, the level of formaldehyde to be considered acceptable is ≤ 75 ppm for children 3 years and older and adults. This same standard is used most by textile dealers and their associations, including the American Apparel and Footwear Association.

The ISO standard of an acceptability level of ≤ 75 ppm for use of formaldehyde in clothing raises the understandable question as to why DOE would require reporting at a level as low as 40 ppm in such instances.[3] The proposed DOE rule could lead the public to assume that formaldehyde in clothing between 40 and 75 ppm is not acceptable because it must be reported. Why else would DOE be interested in receiving the information? To avoid unnecessary confusion, ACC urges DOE to, at a minimum, (1) follow ISO 14184-1, and (2) not recommend a one size fits all testing methodology. As discussed, the proper means for testing textiles is via extraction with water.

* * *

We look forward to working with you and DOE on this rulemaking. If you have any questions, please contact me at 202.249.6704 or at ann_mason@americanchemistry.com. Thank you in advance for considering our comments.

Sincerely,

Ann M. Mason
Senior Director

[2] *See, e.g.,* Organization for Economic Co-Operation and Development: Trade Policy Studies Environmental Requirements and Market Access – ISBN-92-64-01373-3, Chapter 1 - Limits on Formaldehyde in Textiles, 2005.

[3] Draft WAC 173-334-090 (e)(i).

From: Berry, Leslie
To: Williams, John (ECY);
Subject: ACC Ketones Panel Comments on WAC 173-334
Date: Friday, January 07, 2011 10:56:26 AM
Attachments: ACC MEK comments to DOE FINAL 010711.pdf

Mr. Williams,

The ACC's Ketones Panel is submitting the attached comments on the Washington State Department of Ecology's WAC 173-334. Thank you for the opportunity to provide these comments.

Regards,

Leslie Berry
Chemical Products & Technology Division
American Chemistry Council
700 2nd Street, NE, Washington, DC 20002
Ph: (202) 249.6716

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January 7, 2011

SENT VIA ELECTRONIC MAIL

Mr. John R. Williams
Washington State Department of Ecology
W2R HQ
P.O. Box 47775
Olympia, WA 98540-7775
jowi461@ecy.wa.gov

RE: American Chemistry Council Comments on Proposed WAC 173-334

Dear Mr. Williams:

The American Chemistry Council's Ketones Panel[1] ("Panel") appreciates the opportunity to comment on the Washington State Department of Ecology's ("DOE") WAC 173-334[2], proposed regulations to implement the Children's Safe Products Reporting Rule. When finalized, this rule will require manufacturers of children's products to notify the DOE when a chemical of high concern to children (CHCC) is present in their product(s)[3]. The safety of children's products is of the utmost importance, and addressing the potential risks faced by children from possible exposure to chemicals is an important objective of the proposed regulations.

The Panel supports several concepts in the proposed regulation and the objective of, however, we can't support the inclusion of methyl ethyl ketone (MEK) on the DOE's chemicals of high concern to children (CHCC) list because MEK does not meet the criteria for High Priority Chemicals (HPCs) defined in the Children's Safe Product Act (CSPA) (76.240.010 (6)). The Panel therefore requests DOE remove MEK from the proposed CHCC list.

I. REPROTEXT®'s Assessment of MEK is Inaccurate

HPCs are defined in the CSPA (76.240.010 (6)) as follows:

> " High priority chemical means a chemical identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative by the department on the basis of credible scientific evidence as known to do one or more of the following:
> (a) Harm the normal development of a fetus or child or cause other developmental toxicity;

[1]The Ketones Panel members include The Dow Chemical Company, Eastman Chemical Company, and The ExxonMobil Chemical Company.
[2] See http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf
[3] Proposed Rule Text October 22, 2010, Chapter 173-334 WAC Children's Safe Products-Reporting Rule

(b) Cause cancer, genetic damage, or reproductive harm;
(c) Disrupt the endocrine system;
(d) Damage the nervous system, immune system, or organs or cause other systemic toxicity;
(e) Be persistent, bioaccumulative, and toxic; or
(f) Be very persistent and very bioaccumulative."[4]

Review of the DOE's CSPA Pilot Phase 2 Score sheet for MEK[5] reveals that the chemical's severe final toxicity determination is solely reliant on the A- rating, i.e., a classification of MEK as an unconfirmed human reproductive hazard in the REPROTEXT® database. The Panel is concerned fundamentally over the fact that the REPROTEXT® database is not publically available and cannot be reviewed. It is not possible to determine what data were used to make the A- determination. Based on a review of publically available data, the Panel believes that a proper classification of MEK would be B-, few reproductive effects in animals but with no human data. The DOE's reliance on the REPROTEXT® database as the only indicator for MEK's toxicity determination should be considered unsound, in part because this database is not available for review and also because the proposed classification is not consistent with the available reproductive and developmental toxicity data for MEK.

The Panel was unable to access the REPROTEXT® database and could not review the assessment for MEK. Nonetheless, based on MEK's lack of human data indicating reproductive effects, and the relatively few developmental effects in animal studies, we concluded that the REPROTEXT® rating of A- is not accurate. A conservative analysis of the available MEK reproductive and developmental toxicity database summarized in this letter would properly lead to a REPROTEXT® hazard rating of B-. According to the REPROTEXT® database, a B- rating indicates that a chemical's development and reproductive effects are considered only as few reproductive effects in animals but no human effects. According to the DOE's score sheet, a B- REPROTEXT® classification would change MEK's final toxicity determination from a "Serious" to a non-classification justifying the removal of MEK from the DOE's proposed CHCC list.

II. MEK Animal Studies do not Support Developmental of Reproductive Toxicity Effects

There are several MEK developmental toxicity studies in rats and mice which are publically available. The data from these studies indicate that MEK is not embryotoxic or teratogenic, and that MEK does not cause fetotoxicity at doses that do not also cause maternal toxicity. There is also a two-generation reproductive and developmental toxicity study of 2-butanol, which, when absorbed is metabolized to MEK. In this study Cox et al. (1975) demonstrated that the administration of 2-butanol in drinking water to rats at a concentration of

[4] Children's Safe Product Act Report, July 2009 page 16.
[5] See the DOE's Phase 2 Appendix 1 Score sheet for MEK at http://www.ecy.wa.gov/programs/swfa/rules/pdf/p2ss.pdf

3% produced maternal toxicity accompanied by developmental effects, but did not affect reproductive performance. The Cox et al. study was later assessed by the EPA's IRIS program in 2003 and judged to be relevant to an assessment of the potential reproductive hazards of MEK based on metabolic considerations (EPA 2003). Decreased F0 parental weight gain prior to mating, decreased $F1_A$ pup survival, and decreased $F1_A$ pup weights among survivors at postnatal days 4 and 21 were observed in the groups exposed to 3% 2-butanol in the drinking water. At the 2% level (adjusted following $F1_A$ postnatal day 21), the following effects were noted: decreased maternal body weight gain during the second pregnancy of the F0 dams, decreased $F1_B$ fetal weights when pregnancy was terminated at gestation day 20, and decreased F2 pup weights at postnatal days 4 and 21. At the next lower dose level (1%), reduced $F1_A$ pup weight was observed, but the effects on body weights were not observed in subsequent generations at the same exposure level. These studies indicate that 2-butanol, and by extension MEK, do not affect reproductive performance and are not teratogenic. The only fetal effects were indicative of developmental delays and only occurred at levels which affected maternal body weight gain.

In developmental toxicity studies of MEK in which inhalation was used as the route of administration, exposure of pregnant rats to 1,000 or 3,000 ppm 2- butanone during gestation resulted in a slight increase in the incidence of malformations at 3,000 ppm; acaudia and imperforate anus were found in 2 fetuses out of 21 litters, and brachygnathia was noted in 2 other fetuses. A low incidence of sternebral anomalies was also noted in the 3,000 ppm group. The incidence of malformations was not statistically different from that found in the control group (Schwetz et al. 1974).

In a second developmental toxicity study of MEK (Deacon et al. 1981), no statistically significant differences in external or soft tissue abnormalities were found in the offspring of dams exposed to 3000 ppm or less during gestation, no effects were observed on the number of live fetuses/litter or on fetal crown-rump length. Skeletal variations which are regarded as evidence of delayed development but are not malformations such as delayed ossification of the cervical centra, sternebral malformations, and asymmetric pelvis were observed at 3000 ppm. Decreased body weight gain and increased water consumption in the pregnant rats at 3000 ppm MEK indicated that some maternal toxicity may have occurred at this exposure level. Deacon et al. (1981) concluded MEK was slightly fetotoxic, but not embryotoxic or teratogenic at 3000 ppm, a level which was also maternally toxic.

Lastly, a third study showed that mean fetal body weight was reduced in the male and female offspring of mouse dams exposed to 3,000 ppm butanone (MEK), but was significantly reduced only in the males (Mast et al. 1989). There was no significant increase in the incidence of any single malformation, but several malformations which were not observed in the concurrent control group or the controls of contemporary studies were present at a low incidence--cleft palate, fused ribs, missing vertebrae, and syndactyly. An increase in the incidence of misaligned sternebrae was observed in the 3000 ppm group. However, there was no clear dose-response relationship for these findings. The maternal and embryonic NOAEL was

determined to be 1000 ppm. Overall, the data from these studies indicate that MEK is not embryotoxic or teratogenic. It was concluded that MEK does not cause fetotoxicity at doses that do not also cause maternal toxicity.

III. MEK Human Studies do not Support Developmental of Reproductive Toxicity

The human developmental studies available in the scientific literature for MEK are more limited. A study conducted by Sallmén et. al (2007) examined female Portuguese shoe manufacturer workers and a second study examined male military aircraft maintenance workers exposed to jet fuel and solvents. Both studies examined solvent mixtures and not just MEK alone; compounds such as n-hexane and toluene were also present in these mixtures making any interpretation with regards to MEK difficult at best. The results from these studies do not indicate an association between reproductive toxicity and MEK exposure.

IV. Conclusion

In summary, there is no reliable human evidence that MEK causes reproductive or developmental toxicity. The experimental data in animals indicate that although MEK may cause developmental delays at exposure levels which also produce maternal effects, it is not a selective developmental toxicant, it is not teratogenic, and it does not affect reproductive performance. Therefore, MEK does not meet the criteria as outlined as High Priority Chemicals (HPCs) are defined in the CSPA (76.240.010 (6)) and should be removed from the CHCC list. We look forward to working with you and the DOE on this rule making. If you have any questions, please contact me at Leslie_Berry@americanchemistry.com or (202) 249.6716.

Sincerely,

Leslie Berry

Leslie Berry
Ketones Panel Manager,
Chemical Products and Technology

Reference List

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From: Berry, Leslie
To: Williams, John (ECY);
Subject: ACC Oxo Process Panel"s Comments on WAC 173-334
Date: Friday, January 07, 2011 10:44:46 AM
Attachments: OPP Comment WA St DOE 010611 Final.pdf

Mr. Williams,

I am attaching the ACC Oxo Process Panel's comments on WAC 173-334 for the DOE's consideration. Thank you for the opportunity to provide these comments.

Regards,

Leslie Berry
Chemical Products & Technology Division
American Chemistry Council
700 2nd Street, NE, Washington, DC 20002
Ph: (202) 249.6716

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January 7, 2011

SENT VIA ELECTRONIC MAIL

Mr. John R. Williams
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Olympia, WA 98540-7775
jowi461@ecy.wa.gov

RE: American Chemistry Council Comments on Proposed WAC 173-334

Dear Mr. Williams:

The American Chemistry Council's Oxo Process Panel[1] ("Panel") appreciates the opportunity to comment on the Washington State Department of Ecology's ("DOE") WAC 173-334[2], proposed regulations to implement the Children's Safe Products Reporting Rule. When finalized, this rule will require manufacturers of children's products to notify the DOE when a chemical of high concern to children (CHCC) is present in their product(s)[3]. The safety of children's products is of the utmost importance, and addressing the potential risks faced by children from possible exposure to chemicals is an important objective of the proposed regulations.

The Panel supports several concepts in the proposed regulation and the objective of, however, we can't support the inclusion of n-butanol on the DOE's CHCC list. As discussed in this letter, n-butanol does not meet the criteria for a High Priority Chemicals (HPCs) defined in the Children's Safe Product Act (CSPA) (76.240.010 (6)). Additionally, there is no reliable evidence that n-butanol is present in children's products found in the U.S. The Panel therefore requests DOE remove n-butanol from the proposed CHCC list.

I. The DOE's Toxicity Assessment for N-Butanol is Inaccurate

HPCs are defined in the CSPA (76.240.010 (6)) as follows:

[1] The "Oxo Process" refers to an industrial synthesis process which is used to produce alcohols and related oxygenated compounds. The Panel members include The Dow Chemical Company, Eastman Chemical Company, BASF Corporation and Celanese Limited.
[2] See http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf
[3] Proposed Rule Text October 22, 2010, Chapter 173-334 WAC Children's Safe Products-Reporting Rule

> " High priority chemical means a chemical identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative by the department on the basis of credible scientific evidence as known to do one or more of the following:
> (a) Harm the normal development of a fetus or child or cause other developmental toxicity;
> (b) Cause cancer, genetic damage, or reproductive harm;
> (c) Disrupt the endocrine system;
> (d) Damage the nervous system, immune system, or organs or cause other systemic toxicity;
> (e) Be persistent, bioaccumulative, and toxic; or
> (f) Be very persistent and very bioaccumulative."[4]

Review of the DOE's CSPA Pilot Phase 2 score sheet Score sheet for n-butanol[5] reveals that the chemical's severe final toxicity determination is solely reliant on the flawed REPROTEXT®'s A- rating. An A- REPROTEXT® rating classifies a chemical as an unconfirmed human reproductive hazard. The DOE's reliance on the REPROTEXT® database as the only indicator that n-butanol's toxicity determination should be considered unsound because the assessment relies on inaccurate and outdated information outlined in this letter.

The DOE should consider more recent and accurate assessments such as the 2005 Organization for Economic Cooperation and Development Screening Information Data Set (OECD SIDS) Program evaluation of n-butanol to assess the chemical's risk for causing reproductive and developmental toxicity. The OECD SIDS assessments showed that n-butanol is not a reproductive toxicant and only causes developmental toxicity at very high exposure concentrations that also caused severe maternal toxicity. The conclusion of the OECD's review was stated in the Screening Information Assessment Report (SIAR) as follows: "Several studies indicate that n-butanol is not a reproductive toxicant. Female rats exposed to 6,000 ppm (18,000 mg/m^3) throughout gestation and male rats exposed to 6,000 ppm (18,000 mg/m^3) n-butanol for six weeks prior to mating showed no effects on fertility or pregnancy rate. Male rats given n-butanol at 533 mg/kg/day for 5 days had no testicular toxicity. N-butanol produced only mild fetotoxicity and developmental alterations at or near the maternally toxic (even lethal) dose of 8,000 ppm (24,000 mg/m^3) throughout gestation. An entire battery of negative in vitro tests and a negative in vivo micronucleus test indicate that n-butanol is not genotoxic." The No-Observed-Effect-Concentration (NOEC) for developmental toxicity was 3,500 ppm n-butanol.

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[4] Children's Safe Product Act Report, July 2009 page 16.
[5] See the DOE's Phase 2 Appendix 1 Score sheet for n-butanol at http://www.ecy.wa.gov/programs/swfa/rules/pdf/p2ss.pdf

The conclusions of the OECD SIDS Program should be given considerable weight as this assessment was agreed upon by the regulatory authorities from the OECD Member States including the U.S. EPA. The final outcome of the OECD SIDS Program was that the Member States agreed that n-butanol did not represent a risk for reproductive or developmental toxicity and as such, no labels or warnings were required for the chemical. The proposal by the DOE to classify n-butanol as a reproductive and developmental toxicant is not based on the best science and runs counter to the conclusions of world regulatory authorities.

In addition, the CPSA score sheet for n-butanol provides a "Bad" rating under Line 6 of the Developmental or Reproductive Toxicity Section of the score sheet. This is based on a TDLo of 8000 ppm (incidentally this value is from the Nelson, et al., 1989 studies). The value of 8000 ppm as a TDLo is 32-fold higher than the cutoff for a "Bad" rating of >250 ppm. The No-Observed-Adverse-Effect-Concentration (NOAEC) from this same study was 3500 ppm, a level 14-fold higher than the level required for a "Bad" rating (>250 ppm). Since all chemicals can cause adverse effects on reproduction and development if the dose levels or exposure concentrations are raised high enough (to the point of maternal lethality, if necessary), some evaluation of the dose level or exposure concentration should be conducted prior to inclusion of a chemical in the "Bad" category. The Panel believes these large margins-of-exposure between lowest or no adverse effect concentrations should result in a rating of "No" for this section rather than the current "Bad" rating.

A. Review of N-Butanol REPROTEXT® Summary Section

The REPROTEXT® document for n-butanol is not dated so it is impossible to know when it was last updated. There are references from 2010 suggesting that the document is periodically updated. Unfortunately, the review does not consider the majority of the critical studies for n-butanol and has numerous factual errors in its assessment.

For example, the Summary Section of the REPROTEXT® assessment for n-butanol contains the following statement: "A) N-butanol has been mentioned, with other chemicals, as being possibly associated with congenital defects of the CNS in the offspring of occupationally exposed mothers (Holmberg & Nurminen, 1980; Holmberg, 1979)". This statement is simply incorrect. The only mentions of n-butanol in these references are for exposure to the "Referent" population of mothers that had healthy babies and used for comparison to the case control population of exposed mothers. The below table is from the Holmberg & Nurminen, 1980; Holmberg, 1979 studies:

Exposure at Work of 12 Case Mothers Containing Diagnosis of Child's Malformation, Respectively, and of Three Referent Mothers of Healthy Children[6]

Type of exposure	Solvents	CNS Defect
Case		
plastics manufacturing	styrene; acetone	hydrocephaly
leather industry	denatured alcohol + dyes	anencephaly
textile industry	ethylene oxide; alkylphenol + dyes	hydrocephaly
community service (laboratory)	benzene; dichloromethane; methanol; ether	anencephaly
cultural services (museum)	white spirit[a]	hydrocephaly
plastics manufacturing	styrene; acetone	anencephaly
printing and publishing	white spirit	meningomyelocele with hydrocephaly
rubber products manufacturing	toluene; xylene; white spirit; methylethylketone	hydranencephaly
metal products manufacturing	petrol; denatured alcohol	meningocele
metal products manufacturing	toluene	internal congenital hydrocephaly; agenesis of corpus callosum
leather industry	denatured alcohol + dyes	hydrocephaly
building	toluene, white spirit	meningomyelocele
Referent		
equipment manufacturing	xylene, **butanol**	
community services (laboratory)	mixed aromatic/aliphatic	
community services (surgery)	halothane, ether	

[a]Mixture of C7-9 aliphatic hydrocarbons

[6] Table extracted from Holmberg & Nurminen, 1980; Holmberg, 1979

The Summary section also references an article authored by Zajkov et al.. This article is written in Bulgarian and summarized in Russian and English. The Zajkov et al. reference does not provide a basis to conclude that n-butanol should be implicated in complications of pregnancy in humans. According to the article:

> "Concentrations of chemical damages were examined such as, toluol, xylol, acetone, ethyl alcohol, butyl alcohol, isobutyl alcohol, butyl and amyl acetate in air of working zone. The authors investigated morbidity with temporary loss of working capacity of workers in 4 departments of furniture plants for a period of two years.
>
> The obtained results indicated that concentrations of toluol always surpassed the threshold values, but the remaining chemical damages – only in single cases. The total concentration, estimated by the formula of G. Averianov, surpassed many times the conditioned threshold value.
>
> The highest percentage of workers were ill with high indices of morbidity and this was observed among workers, exposed to high concentrations of the chemical damages. In the structure of the morbidity a leading place occupied acute catarrhs of the upper respiratory pathways, followed by complications of pregnancy and neurosis."

Based on the above summary it is evident that n-butanol was involved in a single instance of over-exposure and that the observed effects (acute catarrhs of the upper respiratory pathways, followed by complications of pregnancy and neurosis) were correlated with high toluol (toluene) exposures. Based on this information it is impossible to conclude that n-butanol should be implicated in complications of pregnancy in humans.

B. <u>Review of N-Butanol REPROTEXT®'s TERATOGENICITY Section</u>

The Teratogenicity section contains the following statement:

> "A) ANIMAL STUDIES. 1) Butanol was teratogenic in rats (Ritter, 1985) and is now being studied for teratogenicity (Mankes, 1985). 2) Butanol was teratogenic when injected into chicken embryos (McLaughlin, 1964), producing cataracts, cleft palate, and nerve and kidney damage (McLaughlin, 1963), but the implications of this study for human reproduction are unclear".

Comparison of these references with those used by OECD in the evaluation for the SIDS process is concerning. The most robust study used to evaluate the teratogenicity of n-butanol within the SIDS process were studies conducted by Nelson and coauthors published in 1989 (Nelson, et al., 1989a

and Nelson et al., 1989b). The lead author of these studies was B.K. Nelson, a developmental toxicologist specializing in developmental neurotoxicology at the Division of Biomedical and Behavioral Science at the National Institute for Occupational Safety and Health (NIOSH). The authors concluded that although high concentrations (8000 ppm) of n-butanol produced developmental toxicity, it was at best, a weak developmental toxicant. The NOAEC for maternal animals was 3500 ppm and the NOAEC for offspring was 3500 ppm (based on slight decrease in fetal weight at 6000 ppm). The Panel suggests that the OECD SIDS evaluation be considered as the appropriate measure of the potential risk for developmental toxicity for n-butanol and not the outdated references cited in the n-butanol REPROTEXT® summary.

Moreover, the study cited as "Mankes, 1985" is only an abstract from the 1985 Teratology Society meeting. In this report n-butanol was tested along with ethanol, propanol, 2-chloroethanol, 2-bromoethanol, 2-phenylethanol, 2-aminoethanol and 1,3 butanediol. The abstract actually contains no information on n-butanol developmental effects, however, the developmental effects of the other chemicals are highlighted. The proper conclusion from this abstract is that n-butanol did not cause any developmental effects.

C. Review of N-Butanol REPROTEXT®'s PREGNANCY EFFECTS Section

The Pregnancy effects section of REPROTEXT®'s n-butanol assessment contains the following:

> "A) ANIMAL STUDIES 1) Butanol embryotoxic in rats (Ritter, 1985). 2) Butanol and other higher alcohols have been embryotoxic when given to pregnant rats on about the 12th day of pregnancy. These higher alcohols are thought to be metabolized to their corresponding aldehydes, which may be the active agents (EJ Ritter, personal communication). 3) 1-Butanol has been shown to inhibit formation of phosphatidic acid and astroglial proliferation in rat cortical primary astrocytes. The authors suggest this mechanism may also contribute to the inhibition of astroglial growth and brain development seen in alcoholic embryopathy (Kotter & Klein, 1999)."

The above section can be almost entirely attributed to the Ritter abstract from the 1985 Teratology Society meeting: "Also under study are the alcohols 1-butanol, 1-hexanol, 1-octanol, and 1-decanol, and the corresponding organic acids. Preliminary results indicate that as a class these common chemical compounds exhibit teratogenic properties." This section does not provide any additional information beyond this abstract, and no other studies could be located to validate this claim. Since the Nelson et al., (1989a and 1989b) studies are the most robust developmental toxicity studies, the results of Nelson should be utilized to evaluate the developmental toxicity of n-butanol. As discussed in section B of this letter, Nelson, et al. (1989a and 1989b), concluded that although high

concentrations (8000 ppm) of n-butanol produced developmental toxicity, it was at best, a weak developmental toxicant. The NOAEC for maternal animals was 3500 ppm and the NOAEC for offspring was 3500 ppm (based on slight decrease in fetal weight at 6000 ppm).

Lastly, in Ritter (1985) study that REPROTEXT® relies on n-butanol was exposed directly to primary astrocytes in culture. The inhibition of astroglial proliferation (the focus of that paper), appears to be due to the alcohol itself as astrocytes lack alcohol dehydrogenase to covert the alcohol into its corresponding aldehyde (Iborra et al., 1992). When tested at sub-lethal concentrations, aldehydes did not inhibit DNA synthesis in human astrocytoma cells (Guizzetti and Costa, 1996). The production of aldehydes from alcohols is a well-known metabolic pathway. Reactive aldehydes form Schiff bases with proteins or can be further metabolized to the corresponding acids. Therefore, aldehydes formed from alcohols are quickly eliminated and would require production within the embryo "*in situ*" for them to have an adverse effect on the developing conceptus.

D. Review of N-Butanol REPROTEXT®'s Additional Sections

The Predisposing Conditions section also repeats outdated claims of n-butanol causing ototoxicity. This issue has been investigated, thoroughly refuted and discussed in n-butanol's OECD SIDS documents. Also, the Biomonitoring section claims that the American Conference of Governmental Industrial Hygienists (ACGIH) (2010) had produced a Biological Exposure Indices (BEI) for n-butanol based on the formation of methemoglobin in blood. This is factually incorrect. ACGIH does not have a BEI for n-butanol, and n-butanol does not cause methemoglobin formation. It is unclear where the authors of the REPROTEXT® database obtained this incorrect information. The 2010 ACGIH BEI document is included as a reference with this submission.

II. The DOE's Exposure Assessment for N-Butanol is Does not Support the Findings

The DOE's score sheet assessment for n-butanol does not present any relevant evidence that n-butanol is present in children's products sold in the United States. Review of the exposure section of the DOE's CSPA Pilot Phase 2 Score sheet for n-butanol reveals that the presence of n-butanol in children products relies solely on several studies from the Danish EPA. According to the DOE's 2009 Children's Safe Product Act Report (CSPRA), the DOE reviewed the Danish EPA's studies to determine their relevance to products sold in the U.S. The CSPAR goes on to concluded that, "the Danish data should be used more as an indicator of possible chemicals use and not a confirmation of their presence in the U.S. toys and other children's products."[7] Based on this information the DOE's final exposure determination for n-butanol should be changed from "Known" to a "Possible" classification based on the other information in n-butanol's score sheet assessment. A Possible

[7] Children's Safe Product Act Report, July 2009 page 32.

exposure determination consistent with facts here, does not suggest that n-butanol has been found in children's products in the U.S. and further supports the removal of n-butanol from the DOE's CHCC list.

III. Conclusion

In summary, there is no reliable evidence that n-butanol causes reproductive or developmental toxicity or that n-butanol is present in children's products found in the U.S. Inclusion of the Nelson et al., (1989) studies into the REPROTEXT® evaluation and correction of the frequent mistakes currently included in that database would dramatically change the REPROTEXT® rating for reproductive hazard. A conservative analysis of the n-butanol reproductive an developmental toxicity database included in the 2005 OECD SIDS evaluation would lead to a REPROTEXT® hazard rating of "B-", as the effects were noted only at very high exposure concentrations and at levels causing significant maternal toxicity. The human data does not suggest any cause for concern for n-butanol affecting human reproduction or development.

For the above reason's n-butanol does not meet the criteria as outlined as a High Priority Chemicals (HPCs) are defined in the CSPA (76.240.010 (6)) and should be removed from the CHCC list. We look forward to working with you and the DOE on this rule making. If you have any questions, please contact me at Leslie_Berry@americanchemistry.com or (202) 249.6716.

Sincerely,

Leslie Berry

Leslie Berry
Oxo Process Panel Manager,
Chemical Products and Technology

Reference List

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From: Barbara Losey
To: Williams, John (ECY);
Subject: APERC Comments on WA Children"s Safe Product Reporting Rule, Ch. 173-334
Date: Friday, January 07, 2011 2:46:46 PM
Attachments: APERC Cover Letter for Comments on Washington State CSPR (01.07.2011).pdf
Final APERC Comments on WA Childrens Safe Products Rule(01.07.2011).pdf
FINAL Appendix I to APERC Comments on CH 173-334 (01.07.2011).pdf

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Dear Mr. Williams:

The Alkylphenols & Ethoxylates Research Council (APERC) respectfully submits the attached comments in opposition to the inclusion of 4-Nonylphenol (CAS 104-40-5); Nonylphenol (CAS 25154-52-3); 4-NP and its isomer mixtures (CAS 84852-15-3 and CAS 25154-52-3); Phenol, 4-octyl (CAS 1806-26-4); 4-tert-Octylphenol (CAS 140-66-9); and 1,1,3,3-Tetramethyl-4-butylphenol (CAS 140-66-9) on the Reporting List of Chemicals of High Concern to Children (CHCC List) under section WAC 173-334-140 of the proposed reporting regulation.

APERC is composed of manufacturers, processors and raw material suppliers of alkylphenols and alkylphenol ethoxylates, including nonylphenol (NP) and octylphenol (OP), which are proposed to be Priority Chemicals under Chapter 173-334 . The Council has been in existence for over 25 years with the purpose of promoting the safe use of these compounds through sound science, responsible chemical management and risk-based public policy.

Please do not hesitate to contact me at blosey@regnet.com or (202) 419-1506 if I can be of further assistance, to clarify any comments or if additional information is needed.

Sincerely,

31

Barbara S. Losey

Deputy Director

Enclosures: Comments of the Alkylphenols & Ethoxylates Research Council on Washington Chapter 173-334 (01.07.2011)
Appendix I to APERC Comments (01.07.2011)

31

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Alkylphenols & Ethoxylates Research Council
Comments on
Washington State Children's Safe Product Reporting Rule, Chapter 173-334
Submitted January 7, 2011

The Alkylphenols & Ethoxylates Research Council (APERC) provides the following comments to the Washington State Department of Ecology (DoE) opposing the inclusion of various alkylphenol compounds on the list of Chemicals of High Concern to Children (CHCC) under Chapter 173-334- 140 of the proposed: Children's Safe Products - Reporting Rule. For more than twenty years APERC and its member companies have been actively engaged in toxicological, environmental fate and ecotoxicity research on alkylphenols, including nonylphenol (NP), and octylphenol (OP), and their derivative compounds.[1] Consequently, APERC can contribute considerable information and expertise on the uses, toxicological data and risk assessments available for these compounds.

NP and OP are not intentionally used in any products intended for use by children. NP and OP are chemical intermediates that are used primarily in an industrial setting to produce other derivative compounds such as nonylphenol ethoxylates (NPEs), octylphenol ethoxylates (OPEs) and resins. In addition, the weight of the scientific evidence for these compounds and their derivatives continues to support their safety for humans as well as for children. It is not just APERC that has come to this conclusion; governmental risk assessments conducted by the European Union (EU), Canada and United States Environmental Protection Agency (EPA) have come to the same conclusion.[2] [3] [4] [5] In fact, the EPA has conducted children's health risk assessments on

[1] Current members of the Alkylphenols & Ethoxylates Research Council include: Dover Chemical Corporation; SI Group; TPC Group; and The Dow Chemical Company.
[2] Environment Canada and Health Canada (EC and HC). (2001). Priority substances list assessment report for nonylphenol and its ethoxylates. ISBN: 0-662-29248-0. http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl2-lsp2/nonylphenol/index-eng.php.
[3] European Chemicals Bureau (ECB). (2002). European Union Risk Assessment Report: 4-nonylphenol (branched) and nonylphenol: Final report. http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT.
[4] US Environmental Protection Agency , Office of Prevention, Pesticides and Toxic Substances (US EPA, OPPTS). (2006, July 31). Action memo: Inert reassessments: Four exemptions from the requirement of a tolerance for nonylphenol ethoxylates. Washington, DC, USA.
[5] US Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances (US EPA, OPPTS). (2010, April 5). Memorandum: Alkylphenol Ethoxylates (APEs-JITF CST 5 Inert Ingredients). Revised Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations., Washington, DC, USA.

nonylphenol ethoxylates (NPE) and octylphenol ethoxylates (OPEs) under the Food Quality Protection Act (FQPA) that approved these compounds for use as inert ingredients on food crops after concluding "no concern for increased sensitivity to infants and children from NPE" and "long-term aggregate risks are not of concern" (including childrend) for OPE. [6] [7]

Where governmental agencies have taken risk management actions related to NP and NPE they were driven by concerns due to aquatic toxicity – not endocrine effects and not human health concerns.NP and OP do not warrant regulation in Washington as CHCCs; therefore there is no need for DoE to collect product use and exposure information or to otherwise regulate these compounds under Chapter 173.334.

The following comments are provided in support of APERC's position opposing the inclusion of various NP and OP compounds on the CHCC list.

1.0 NP AND OP ARE NOT USED DIRECTLY IN ANY PRODUCTS SPECIFICALLY INTENDED FOR USE BY CHILDREN.

1.1 Nomenclature and Chemical Abstract Service (CAS) numbers for NP and OP

The nonyl group of NP consists of numerous highly branched isomers and is located primarily at the *para* position on the benzene ring, although minor amounts of *ortho* isomers may also present. In contrast, OP is primarily a single isomer, 4-(1,1,3,3-tetramethylbutyl)phenol with the alkyl group located at the para position of the benzene ring. [8]

The following nomenclatures and CAS numbers are listed for NP and OP in Section 173-334-140 of the proposed Children's Safe Products - Reporting Rule: 4-Nonylphenol (CAS 104-40-5); Nonylphenol (CAS 25154-52-3); 4-Nonylphenol and its isomer mixtures (CAS 84852-15-3 and CAS 25154-52-3); Phenol, 4-octyl (CAS 1806-26-4); 4-tert-Octylphenol (CAS 140-66-9); and 1,1,3,3-Tetramethyl-4-butylphenol (CAS 140-66-9). In these comments, as in commerce generally, NP refers to all nomenclatures and CAS numbers (except those relating to linear nonylphenol) describing branched NP and OP refers to all nomenclatures and CAS numbers describing OP.

[6] US EPA, OPPTS. (2006, July 31).
[7] US EPA, OPPTS. (2010, April 5).
[8] Staples, C.A., Klecka, G.M., Naylor, C.G., & Losey, B.S. (2008). C8- and C9-alkylphenols and ethoxylates: I. Identity, physical characterization, and biodegradation pathways analysis. Human and Ecological Risk Assessment, 14 (5), 1007–1024.

1.2 NP and OP are used as intermediates in the production of other compounds, such as nonylphenol ethoxylates (NPEs), octylphenol ethoxylates (OPEs) or resins.

NP and OP are used as isolated and contained intermediates in the production of other derivative compounds. NP is used primarily as a raw material in the manufacture of NPE; however some is also used in the production of plastics, resins and stabilizers. OP is produced in significantly lower volumes and is used primarily as a chemical intermediate in the production of phenolic resins.

APERC is only aware of one direct use of NP in a consumer product as a catalyst in epoxy resin hardeners.[9] Epoxy resins are used in fiber reinforced composites where a high strength-to-weight ratio is necessary (e.g., automobiles, bikes, snowboards, skies, golf clubs, boat hulls and interior components such as bulkheads); they are especially popular in boat repairs. Epoxy components bond very well to all types of surfaces and are used in floor coatings, paints and metal coatings. In these epoxy resin applications NP is expected to remain encapsulated in the polymer matrix. Therefore, exposure of consumers and children to NP from their use in epoxy resins is expected to be incidental and very low.

1.3 The use of NPE and OPE in consumer products has declined and these compounds are now used primarily in industrial applications.

NPE and OPE are produced by the reaction of the relevant alkylphenol with ethylene oxide (EO) to produce molecules with a single chain of EO units. Production of these alkylphenol ethoxylates (APEs) is the primary use of NP and to some extent OP. In the United States, market pressures driven by risk management actions taken in other regions to address concerns related to the aquatic toxicity of NP and NPE have resulted in significant reformulation away from NPE in many consumer product applications.

NPEs are now used primarily in the following institutional and industrial applications.[10]

- Industrial and institutional cleaning
- Coatings
- Agriculture
- Pulp and paper processing
- Textile manufacture and processing

[9] Wolfram, W., SI Group (2010, October 6) Personal Communication to the Alkylphenols & Ethoxylates Research Council on Uses of Nonylphenol.
[10] Janshekar, Hossein; Chang, R. J.; Yokose, Kazuteru; and Ma, Xaomeng. (2007, October). SRI Consulting Report: Surfactants. Menlo Park, CA USA.

OP is primarily used in the manufacture of resins. The intentional use of either of these compounds in children's products proposed for regulation under the Children's Safe Product Reporting Rule is not expected to be significant.

2.0 NP AND OP DO NOT WARRANT REGULATION AS HIGH PRIORITY CHEMICALS OF CONCERN TO CHILDREN (CHCC) SINCE THEY DO NOT MEET THE CRITERIA AS SUCH

"High priority chemical" is defined under Washington State RCW 70.240.010(6) as "a chemical identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative by the department on the basis of credible scientific evidence as known to do one or more of the following:(emphasis added)

(a) Harm the normal development of a fetus or child or cause other developmental toxicity;
(b) Cause cancer, genetic damage, or reproductive harm;
(c) Disrupt the endocrine system;
(d) Damage the nervous system, immune system, or organs or cause other systemic toxicity;
(e) Be persistent, bioaccumulative, and toxic; or
(f) Be very persistent and very bioaccumulative."

The framework for evaluating these characteristics is described in the Children's Safe Product Act Report (the Report) as being based on "evidence describing the chemical with respect to endpoints of highest concern for children: developmental and reproductive toxicity, endocrine disruption, cancer" along with the "strength and weight of the evidence for those health endpoints".[11]

NP and OP are not listed on most of the authoritative source lists that are identified in Appendix 2 of the Report and were used to develop the CHCC list. Following is a summary of the findings and relevance in cases where NP and/or OP are listed by any of the authoritative source lists. This review supports APERC's position that NP and OP should not be on the CHCC list based on the criteria for "High Priority Chemical" as defined under Washington State RCW 70.240.010(6).

2.1 NP and OP are not persistent or bioaccumulative - and therefore not "very persistent" or "very bioaccumulative" - as determined by various governmental sources, including, in the case of NP, Washington State's own PBT Program.

[11] Washington State Department of Ecology (WA DoE).(2009, July). Children's Safe Product Act Report. Publication No. 09-07-014

The terms "persistent" and "bioaccumulative" have very specific scientific meanings and are based on measurable criteria. Assessments of the persistence and bioaccumulation of NP, OP and their ethoxylates relative to recognized criteria have been conducted by the EU, Environment Canada, the state of Oregon and Washington State DoE.[12,13,1415,1617, 18 19]

With the exception of the Oslo-Paris Commission (OSPAR), all of the source lists used to develop the CHCC list concluded that NP and OP, along with their ethoxylates, are not persistent or bioaccumulative. Therefore, DoE should not rely on the classifications by OSPAR of NP (as persistent and possibly bioaccumulative) and OP (as persistent but not bioaccumulative), especially considering that other authoritative sources used to develop the CHCC have determined NP and OP are not persistent or bioaccumulative.

2.1.1 The European Commission determined NP is NOT persistent or bioaccumulative.

In 2003, the European Commission (EC) Joint Research Centre Institute for Health and Consumer Protection, one of the source lists used to compile the CHCC list, conducted an assessment for NP and concluded it does not meet the EC criteria to be classified as persistent or bioaccumulative.[20 21]

2.1.2 Environment Canada determined NP/NPE and OP/OPE are NOT persistent or bioaccumulative.

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[12] European Chemicals Bureau PBT Working Group (ECB PBT WG). (2003). Substance Information Sheets for Nonylphenol (CAS 25154-52-3) and Phenol, 4-Nonyl, branched (CAS 84852-15-3).
[13] Environment Canada (EC). (2006). Ecological categorization of substances on the Domestic Substance List; Categorization Decisions. http://www.ec.gc.ca/substances/ese/eng/dsl/cat_index.cfm.
[14] Environment Canada (EC). (2005, November 21). Decision Letter to Alkylphenols & Ethoxylates Research Council Regarding Environment Canada's Preliminary Categorization of Nonylphenol, Octylphenol and their Ethoxylates
[15] Washington State Department of Ecology (WA DoE). (2006a, January). Rule Adoption Notice: Persistent Bioaccumulative Toxins Chapter 173-333 WAC. http://www.ecy.wa.gov/biblio/0607007.html
[16] Washington State Department of Ecology(WA DoE). (2006b, January) Concise Explanatory Statement and Responsiveness Summary for the Adoption of Chapter 173-333 WAC Persistent Bioaccumulative Toxins. Publication: 06-07-006. http://www.ecy.wa.gov/biblio/0607006.html
[17] Oregon Department of Environmental Quality (OR DEQ). (2009, October). Final Report: Senate Bill 737: Development of a Priority Persistent Pollutant (P3) List for Oregon. No. 09-WQ-013. http://www.deq.state.or.us/wq/SB737/docs/P3LReportFinal.pdf.
[18] Environment Canada (EC). (2006).
[19] Environment Canada (EC). (2005, November 21).
[20] European Commission(EC). (2002). Identification of potential PBTs or vPvBs among the IUCLID high production volume chemicals. European Chemicals Bureau Doc. ECB 4/14/02. August 30, 2002
[21] EC (European Commission). 2003. Minutes of Third Meeting of TM Subgroup on Identification of PBT and vPvB Substances. Arona, Italy. October 27-28, 2003

In 2005, Environment Canada completed a review of NP/NPE and OP/OPE as part of a categorization assessment under the Canadian Environmental Protection Act (CEPA), which required an assessment of all substances on the Canadian Domestic Substances List (DSL) with respect to persistence, bioaccumulation and inherent toxicity (PBiT) characteristics. Environment Canada concluded that none of these compounds are persistent or bioaccumulative according to the CEPA criteria.[22] The Canadian chemical categorization and prioritization program under CEPA is also one of the source lists used to compile the CHCC list.

2.1.3 Washington State DoE itself determined NP is NOT persistent or bioaccumulative.

In 2006, the Washington State DoE removed NP from its list of PBT chemicals in a final rule on PBT substances (Chapter 173-333 WAC).[23] [24]APERC submitted extensive comments in support of this action. [25] The Washington PBT list is one of the other source lists used to compile the CHCC list.

2.1.4 The State of Oregon determined NP and OP are NOT Persistent or Bioaccumulative.

In 2009, the Oregon Department of Environmental Quality (DEQ) assessed NP and OP in the development of that state's Priority Persistent Pollutant List (P3L) and removed both from the P3L because neither is persistent or bioaccumulative. NP and OP also did not meet OR DEQ's human health criteria for listing on the P3L.[26]

2.1.5 The Oslo-Paris Commission (OSPAR) incorrectly characterizes the persistence and/or bioaccumulation properties of NP and OP and should not be used as a source for the CHCC list.

The OSPAR Chemicals for Priority Action list is the only source used in the development of the CHCC list that concludes that NP and OP are either persistent or bioaccumulative. The weight-of-evidence for these two compounds does not support this conclusion. It is important to remember that the mission of the OSPAR Commission is to protect the marine environment of the North-East Atlantic and while NP/NPEs and OP have been identified by that organization as potential risk to ocean-dwelling organisms, the OSPAR documents on these compounds <u>do not cite human health concerns</u> as a reason for listing

[22] Environment Canada (EC). (2005, November 21). Decision Letter to Alkylphenols & Ethoxylates Research Council Regarding Environment Canada's Preliminary Categorization of Nonylphenol, Octylphenol and their Ethoxylates.
[23]WA DoE. (2006a, January).
[24] WA DoE. (2006b, January).
[25] Alkylphenols & Ethoxylates Research Council (APERC). (2005, September 29) Comments on Washington State Revised Version of Proposed PBT Rule, Chapter 173-333.
[26] Oregon Department of Environmental Quality (OR DEQ). (2009, October).

them chemicals for Priority Action.[27] [28] For this reason, the OSPAR List of Chemicals for Priority Action (2001, Updated 2004) is not an appropriate source list for Washington State's CHCC list, which is intended to protect children's health.

2.1.6 In addition to the above governmental assessments, numerous laboratory and field studies are available to DoE on the persistence and bioaccumulative properties of NP/NPE and OP/OPE ; a summary of these data was most recently presented in a pair of companion manuscripts by Staples et al. (2008) and Klecka et al. (2008).

The companion papers by Staples et al. (2008) and Klecka et al. (2008) summarize and provide references to the available data on the environmental fate, persistence and bioaccumulative properties of NP and NPE.[29, 30] As such, numerous high quality studies are available to DoE to confirm that NP/NPE and OP/OPE are not persistent or bioaccumulative.

2.2 The Report cites the European Commission (EC) Endocrine Disruptor Program (EDP) Endocrine Disruptor List as a source for the CHCC list; however NP and OP do not meet the EDP criteria for high concern for human exposure; therefore, these compounds should be removed from the CHCC list.

The EC EDP list clearly states that it is a "list of substances for further evaluation of their role in endocrine disruption"; therefore it does not provide credible scientific evidence that listed substances are known to cause endocrine disruption, as required by RCW 70.240.010(6). The EC EDP states the priority list of chemicals developed within the EU Strategy for Endocrine Disrupters will be used to prioritize them for further detailed review. It is important to remember that the chemicals on the list have not undergone any type of risk assessment and the list is not regarded as final and unchangeable; addition and removal of chemicals may occur in response to either developments in scientific

[27] Oslo Paris Commission (OSPAR). (2001, 2004 Update). Hazardous Substance Series: Nonylphenol/ Nonylphenol ethoxylates. Publication No. 136/2004. http://www.ospar.org/documents/dbase/publications/p00136_BD%20on%20nonylphenol.pdf

[28] Oslo Paris Commission (OSPAR). (2003, 2006 Update). OSPAR Background Document on Octylphenol. Publication Number: 273/2006

[29] Staples, C.A., Klecka, G.M., Naylor, C.G., and Losey, B.S. (2008). C8- and C9-Alkylphenols and Ethoxylates: I. Identity Physical Characterization, and Biodegradation Pathways Analysis Human and Ecological Risk Assessment, 14: 1007–1024.

[30] Klecka, G.M., Staples, C.A., Naylor, C.G., Woodburn, K.B., and Losey, B.S. (2008). C8- and C9-Alkylphenols and Ethoxylates: II. Assessment of Environmental Persistence and Bioaccumulation Potential .Human and Ecological Risk Assessment, 14: 1025–1055.

knowledge or changes in chemical usage patterns.[31] On this basis alone, the use of this list as a source list for CHCC list is questionable.

Also, DoE should consider in more depth the process and findings for the specific compounds in the Program. EC EDP grouped a preliminary list of "suspected endocrine disruptors" into three categories as described below.

> Category 1 - evidence of endocrine disrupting activity in at least one species using intact animals;
> Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption; and,
> Category 3 - no evidence of endocrine disrupting activity or no data available.

The EC EDP report highlights the fact that the Category 1 compounds were not determined using a weight-of-evidence approach. For the 66 chemicals assigned to Category 1, an additional review was conducted to determine if humans or wildlife might actually be exposed to the compounds. [32] Highest concern was assigned to those compounds where "human or wildlife were expected to be exposed." Medium concern related to those where "humans were not expected to be exposed but wildlife could be." Lowest concern was scored for those where "neither humans nor wildlife were exposed."

NP and OP are among the Category 1 compounds assigned a medium level of concern for exposure, based on the finding that "humans were not expected to be exposed but wildlife could be." Since the CHCC list is specifically related to human exposure, this finding for NP and OP should be considered as not supporting prioritization of these compounds as on the CHCC.

3.0 OTHER IMPORTANT GOVERNMENTAL ASSESSMENTS AND OTHER AVAILABLE SCIENTIFIC STUDIES ON THESE COMPOUNDS SUPPORT THE CONCLUSION THAT NP AND OP DO NOT MEET THE CHCC CRITERIA.

Several relevant governmental risk assessments are available, which address the exposure of humans and/or children to NP/NPE and/or OP/OPE through the use of consumer products. Risk assessment is the most scientifically defensible and broadly accepted methodology to prioritize chemicals for regulatory action. By considering relevant human health risk assessments, DoE could ensure that those CHCC chemicals most likely to cause harm to children would be addressed first. This approach is consistent with the

[31] European Commission Endocrine Disruptors Strategy Website (Accessed August 2010) http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#sub2.

[32] European Commission Endocrine Disruptors Strategy. (2000, June). Final Report: Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting. Annex 15: List of 66 Substances with Classification of High, Medium or Low Exposure Concern. http://ec.europa.eu/environment/docum/pdf/bkh_annex_15.pdf

intent in the original legislation to leverage existing governmental work as well as to provide focus on the highest risk compounds on the CHCC list. Certainly if governmental lists can be viewed as legitimate information sources in the development of the Chemicals of High Concern list, then governmental risk assessments, which are more scientifically robust, should also be viewed as acceptable information sources to assist in prioritizing that list.

A review of governmental risk assessments shows that where governmental agencies have taken risk management actions related to NP and NPE they were driven by concerns due to aquatic toxicity – not endocrine effects and not human health concerns. Actions to discourage the use of OP/OPE as substitutes for NP/NPE were also based on environmental concerns. In the United States, EPA finalized federal Water Quality Criteria (WQC) for NP to protect fish and aquatic species in 2006. [33, 34] The states are now implementing these as criteria in their Water Quality Standards under the Clean Water Act.

If DoE does not incorporate conclusions from several existing governmental risk assessments on the human safety of NP/NPE, they will do a disservice to the citizens of Washington State by misdirecting DoE and business resources to promulgate and respond to a regulation on compounds that have been found not to be a risk to human or children's health in the following assessments.

3.1 EPA assessments of the human safety of NPEs and OPEs approved their use as inert ingredients in pesticide formulations after considering risk to infants and children and finding "reasonable certainty of no harm".

Assessments of chemicals by EPA under the Food Quality Protection Act (FQPA) are conducted based on informed multiple risk exposure scenarios, which allows meaningful, risk-based priority setting and activity planning. In 2006, EPA conducted an assessment on the use of NPEs as inert ingredients in pesticide products. More recently, EPA conducted a similar assessment on OPE in 2010. These assessments were conducted as part of a reassessment of all inert ingredients as mandated by Food Quality Protection Act (FQPA).[35] A primary focus of FQPA is children's health. FQPA assessments require the use of reliable data and must make a "reasonable certainty of no harm" finding to exempt an inert ingredient from the requirement of tolerance levels in pesticide products.

[33] US Environmental Protection Agency (US EPA). (2006, February 23). Notice of availability of final aquatic life ambient water quality criteria for nonylphenol. Federal Register, 71 (36), 9337-9339. http://www.epa.gov/EPA-WATER/2006/February/Day-23/w2558.htm.
[34] US Environmental Protection Agency (US EPA). (2005). Aquatic life ambient water quality criteria - nonylphenol. Report 822-R-05-005. US Environmental Protection Agency, Washington, DC, USA. http://www.epa.gov/waterscience/criteria/nonylphenol/final-doc.pdf
[35] US EPA, OPPTS. (2006, July 31).

The EPA inert reassessment on NPE:

- Concluded there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to NPEs when used as an inert ingredient in pesticide products when considering dietary exposure and all non-occupational exposures;
- Acknowledged several multi-generation reproduction studies on NP in rats that demonstrate no adverse effects on reproductive function;
- Found that in NPE developmental toxicity studies in rats and mice, there was no incidence of developmental toxicity in the absence of maternal toxicity;
- Concluded NP/NPE are not carcinogenic;
- Concluded human exposure to NPEs via food, drinking water and residential exposure pathways is orders of magnitude less than the No Observed Effect Levels (NOELs) and No Observed Adverse Effect Levels (NOAELs) in animal studies including chronic, repeat-dose, developmental and carcinogenicity studies; and,
- Concluded no concern at this time for increased sensitivity to infants and children from NPEs.

The EPA inert reassessment on OPE:

- Considered available data on NP and OP, including those related to endocrine activity, to establish dietary endpoints for both the parent compound (OPE) and OP;
- Considered the toxicity database to be sufficient to address potential hazards to humans and children;
- Found there was no evidence of neurotoxicity, developmental toxicity or reproductive toxicity in an OECD 422 study on OPE;
- Regulated on the most sensitive endpoints seen in the database; effects which are well characterized with clear No Observable Adverse Effect Limits (NOAEL)s.[36]

3.2 A Canadian Risk Assessment of NP/NPE concluded no danger to human health from environmental exposures, including from ambient and indoor air, drinking water, foodstuffs and the use of consumer products.

In 2001, Environment Canada and Health Canada conducted a Risk Assessment for NP and NPEs pursuant to the Canadian Environmental Protection Act (CEPA).[37] The

[36] US EPA, OPPTS (2010, May 17)
[37] EC and HC. (2001).

Assessment considered the environmental fate and effects of NP/NPEs along with their human safety and issues relating to endocrine activity.

CEPA requires the evaluation of a chemical's risk potential under three different sections of the law, which includes consideration of the toxicological properties of a substance as well as its concentrations in the Canadian environment. The Canadian Assessment concluded that NP/NPEs were not toxic under either Section 64(b) posing "no danger to the environment on which life depends;" not toxic under Section 64(c) posing "no danger to human health from environmental exposure" and were "not considered a priority — to reduce public exposure through control of sources that are addressed under CEPA." The Assessment did conclude that NP/NPEs were toxic under CEPA Section 64(a) because of the environmental presence of NP and NPEs from untreated or partially treated textile mill effluents that discharge directly to the aquatic environment and because of discharges of NP and NPEs "from a select number of municipal wastewater treatment plants and pulp and paper mills." [38]

Rather than addressing the need for better wastewater treatment in these locations, Environment Canada implemented a regulation requiring that Pollution Prevention (P2) plans be prepared and submitted by Canadian manufacturers and importers of certain types of products (cleaning products, wet textile processing and paper processing) that contain NP/NPEs.

Human exposures considered in the CEPA assessment include exposures from ambient and indoor air, drinking water, foodstuffs and the use of consumer products. The Canadian assessment concluded "NP and NPEs are not considered a priority for investigation of options to reduce human exposure through control of sources that are addressed under CEPA 1999".[39]

The Canadian assessment emphasized that worst case assumptions about exposure to these compounds via skin contact were used in their assessment. A study published subsequently in 2003 determined that the skin absorption of NP and NPEs is less than 1%,[40] confirming that the Canadian assumptions were extremely conservative.

The Canadian assessment also considered the potential for these chemicals to demonstrate estrogenic activity. It concluded NPEs of longer chain lengths (NPE4, NPE9 and NPE12), were not estrogenic in *in vivo* (conducted on living animals) studies

[38] EC and HC. (2001).
[39] EC and HC. (2001).
[40] Monteiro-Rivere, N.A., Van Miller, J.P., Simon, G.S., Joiner, R.L., Brooks, J. and Riviere, J.E. (2003) In Vitro Percutaneous Absorption of Nonylpheonl (NP) and Nonylphenol Ethoxylates (NPE-4 and NPE-9) in Isolated Perfused Skin. Journal of Toxicology: Cutaneous and Ocular Toxicology. Vol. 22, Nos 1 & 2, pp 1-11.

and in a sensitive *in vitro* (laboratory) test. [41] These longer chain NPEs are the ingredients found in the products that are used in industrial and consumer applications.

The Canadian Assessment also concluded "NP was estrogenic only at relatively high doses". In fact, those studies that have shown NP to have any estrogenic activity have shown only very weak activity – ten thousand to one million times less potent than the natural estrogen found in the human body.

3.3 European Commission Risk Assessment on NP concluded no concern for human health.

In a risk assessment finalized in 2002, the European Commission (EC)considered worst-case consumer and work place exposures to residual NP from the use of products that contain NPE. However, even assuming these exposures occur together on a daily basis, the EC Risk Assessment concluded "no concern for human health" and noted there is also sufficient confidence in the Margins of Safety that even if similar low exposures were to occur from one or two other product types there would still be no cause for concern for human health.[42]

The EC assessment concluded, based on estimated environmental exposures or Predicted Environmental Concentrations (PECs), that there were concerns about risk of NP and NPE to fish and other aquatic species in the European Union. [43]

4.0 Evidence of estrogenic activity does not necessarily indicate adverse effects via endocrine disruption; therefore compounds, like NP and OP, which have not "been shown to be" endocrine disruptors by demonstrating adverse effects should not be included on the CHCC list.

While NP and OP display weak estrogenic activity in screening studies (one thousand to one million times less potent than human estrogen) the real test of whether a compound is an endocrine disruptor is not in the screening test, it is in robust multigenerational rat studies that look at adverse effects that are mediated by hormones. Not all substances that have weak hormonal activity in screening assays will produce adverse effects in intact animals. Like natural substances with weak estrogen-like activity (e.g. phytoestrogens found in healthy food sources), NP and OP do not show adverse effects in whole animals except at extraordinarily high doses.[44] [45] [46]

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[41] EC and HC. (2001).
[42] ECB. (2002).
[43] ECB. (2002).
[44] Van Miller, J.P., & Staples, C.A. (2005). Review of the potential environmental and human health-related hazards and risks from long-term exposure to p-tert-octylphenol. Human and Ecological Risk Assessment, 11 (2), 319–351
[45] Tyl, R.W., Myers, C.B., Marr, M.C., Brine, D.R., Fail, P.A., Seely, J.C., & Van Miller, J.P. (1999). Two-generation reproduction study with para-tert-octylphenol (OP) in rats. Regulatory Toxicology and Pharmacology, 30 (2), 81-95.

EPA's Endocrine Screening and Testing Advisory Committee (EDSTAC) is a multi-stakeholder group that developed the conceptual framework and principles by which the EPA will screen and test chemicals for potential endocrine disrupting properties. The EDSTAC evaluates and validates the screens to identify endocrine activity in compounds and the study protocols to identify whether a compound is an actual endocrine disruptor.

The best definitions of "endocrine disruptor" come from EDSTAC and the International Programme on Chemical Safety (IPCS). EDSTAC agreed to the following general definition of an endocrine disruptor:

> *"… an endocrine disruptor is an exogenous chemical substance or mixture that alters the structure or function(s) of the endocrine system* ***and causes adverse effects at the level of the organism****, its progeny, populations, or subpopulations of organisms, based on scientific principles, data, weight-of-evidence, and the precautionary principle*."[emphasis added*]* [47]

The IPCS in their Global Assessment of Endocrine Disrupting Compounds (EDCs) states that:

> *"An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and* ***consequently causes adverse health effects in an intact organism,*** *or its progeny, or (sub)populations.*
>
> *A potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations."* [emphasis added] [48]

Most noteworthy, for a chemical to be considered an endocrine disruptor, the endocrine mediated effects must occur in a whole organism and they must be adverse. IPCS stresses that:

> *"Endocrine disruption is not considered a toxicological end point per se but a functional change that may lead to adverse effects."*

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[46] Tyl, R.W., Myers, C.B., Marr, M.C., Castillo, N.P., Seely, J.C., Sloan, C.S., Veselica, M.M., Joiner, R.L., Van Miller, J.P., & Simon, G.S. (2006). Three-generation evaluation of dietary para-nonylphenol in CD (Sprague-Dawley) rats. Toxicological Sciences, 92, 295-310.

[47] Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) (1998, August). EDSTAC Final Report. http://www.epa.gov/endo/pubs/edspoverview/finalrpt.htm

[48] World Health Organization, International Programme on Chemical Safety (WHO, IPCS). (2002). Global assessment of the State-of-the-science of endocrine disruptors, In *WHO/PCS/EDC/02.2*. Edited by T. Damstra, S. Barlow, A. Bergman, R. Kavlock, and G. Van Der Kraak, eds. Geneva, Switzerland: World Health Organization, International Programme on Chemical Safety.

Thus, chemicals that show some endocrine modulation (e.g., estrogenic, androgenic, thyroidogenic) are not necessarily endocrine disruptors and should not be considered to be such.

The U.S. Environmental Protection Agency makes this same point in their multiple tiered Endocrine Disruption Screening Program (EDSP), where results from Tier 1 screening tests (which may indicate potential endocrine activity) are not indications of definitive "endocrine disruption". Rather results from Tier 2 multigenerational toxicity tests with intact organisms determine whether a substance may cause endocrine-mediated effects through or involving various hormone systems.[49]

4.1 Numerous chronic and multi-generational mammalian toxicity studies are available for NP and/or NPEs; results do not suggest concern for reproductive or developmental effects from *in utero* and\or early life stage exposures to these compounds

Traditional toxicological studies in rats that measure chronic effects (due to long-term exposure) and/or monitor effects in parents and offspring over multiple generations often include an evaluation of reproductive and developmental effects that are indicative of an endocrine mode of action. Numerous studies – some conducted over two or three generations – have evaluated whether the weak estrogenic activity of NP affected reproductive or developmental end points in rats.[50,51,52,53, 54,55] These studies uniformly concluded that there are no effects on reproductive function or performance from NP at any of the doses tested.

NP has been found in four different multigenerational rat studies not to be a reproductive and developmental toxicant. [56, 57, 58 59] The largest of these studies was a five-generation

[49] US EPA Endocrine Disruption Screening Program (EDSP) (Accessed January 6, 2011). http://www.epa.gov/endo/index.htm.
[50] Latendresse, J.R., Weis, C.C., Mellick, P.W., Newbold, R.R., & Delclos, K.B. (2004). A five generation reproductive toxicity assessment of p-nonylphenol (NP) in CD Sprague-Dawley rats. The Toxicologist, 78, 219.
[51] Nagao, T., Wada, K., Marumo, H., Yoshimura, S., & Ono, H. (2001). Reproductive effects of nonylphenol in rats after gavage administration: A two-generation study. Reproductive Toxicology, 15 (3), 293-315.
[52] Odum, J. and Ashby, J. (2000). Neonatal Exposure of Male Rats to Nonylphenol Has No Effect on the Reproductive Tract. Toxicological Sciences, 56, 400-404.
[53] Odum, J., *et al*. (1999). Effects of p-nonylphenol (NP) and diethylstilboestrol (DES) on the Alderley Park (Alpk) Rat: Comparison of mammary gland and uterus sensitivity following oral gavage or implanted mini-pumps. Journal of Applied Toxicology 19, 367-378
[54] Cunny, H.C., et al. (1997). Subchronic Toxicity (90-Day) Study with *para*-Nonylphenol in Rats. Regulatory Toxicology and Pharmacology, 26, 172-178.
[55] Tyl, R.W. *et al*. (2006)
[56] Latendresse, J.R. *et al* (2004).
[57] Nagao, T. *et al*. (2001).
[58] Tyl, R.W. *et al*. (2006).
[59] Chapin, R.E., Delaney, J., Wang, Y., Lanning, L., Davis, B., Collins, B., Mintz, N., & Wolfe, G. (1999). The effects of 4-nonylphenol in rats: A multigeneration reproduction study. Toxicological Sciences, 52, 80-91.

rat study with continuous exposure to NP conducted by the United States National Institute of Environmental Health Science.[60] The data from these studies consistently confirm extremely low systemic concentrations of NP under scientifically valid exposure scenarios and a lack of concern for the weak estrogen-like effects of NP and provide overwhelming scientific evidence that NP does not impair fertility, reproductive capacity in parents or offspring, or development in offspring.

These findings are consistent with and support the results of a five-generation rat study conducted by the US National Institute of Environmental Health Sciences, which concluded that "NP was not a selective reproductive or developmental toxicant."[61] Another study by Tyl et al (2006) determined that there were no adverse effects on sperm following three generations of exposure to NP in rats.[62]

4.2 Chronic and multi-generational mammalian toxicity studies are also available for OP, which do not suggest concern for reproductive or developmental effects from *in utero* and\or early life stage exposures to this compound

A multigeneration reproductive study by Tyl et al (1999) with OP in rats is recognized as the definitive evaluation of reproductive effects, via estrogenic or other mechanisms, for this compound. [63] The study confirmed the lack of estrogen-like activity below levels of metabolic saturation that occur at high exposure doses of OP. A review paper that compared the weight of evidence for mammalian data and compared the results of definitive reproductive assays to to those of screening tests for OP found that estrogen-like activity in screening tests is not predictive of results from definitive testing and that risk assessment decisions for this and other compounds with estrogenic activity should be made using conventional toxicity endpoints. [64]

5.0 Other Toxicological Studies that Support the Human Safety of NP and OP are also available.

Research has confirmed that ingested NP are rapidly broken down into compounds that are not estrogenic and are eliminated within 24 hours. [65] This study, conducted on rats, also confirmed that no significant accumulation of NP occurs in any body organ or tissues following dosing at levels exceeding real-world exposure estimates.

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[60] Latendresse, J.R. *et al.* (2004).
[61] Latendresse, J.R. *et al.* (2004).
[62] Tyl. R.W. *et al.* (2006).
[63] Tyl, R.W. *et al* (1999).
[64] Van Miller, J.P., & Staples, C.A. (2005).
[65] Green, T. *et al.* (2003) Absorption, bioavailability, and metabolism of para-nonylphenol in the rat. Regulatory Toxicology and Pharmacology. 38: 43-51.

A substantial body of evidence on the absorption, metabolism, and excretion of OP indicates rapid first-pass liver metabolism with no accumulation in tissues at doses below those that saturate the capacity of the liver to metabolize this chemicals. At doses below saturation half-lives for OP in blood range from 5.2 to 36 hours. [66]

As noted previously, governmental assessments have also confirmed that NP, OP and their ethoxylates do not bioaccumulate and concluded that they do not pose a risk to humans, or susceptible populations such as children. [67, 68, 69, 70]

6.0 GOVERNMENTAL ASSESSMENTS OF CONSUMER EXPOSURE TO NP AND OP -- AS WELL AS STUDIES THAT SPECIFICALLY EXAMINE EXPOSURE OF PRESCHOOL CHILDREN -- INDICATE THAT EXPOSURE TO THESE COMPOUNDS IS EXTREMELY LOW AND MARGINS OF SAFETY FOR ALL EFFECTS ARE EXTREMELY HIGH

As previously noted, with very few exceptions NP and OP are not used directly in any application intended for use by children. In addition, APERC understands that the use of NPEs and OPEs in detergents and household cleaning products, which are not intended for use by children but could result in incidental exposure, has significantly decreased. The use of these compounds in personal care products has never been significant. Volumes of OP in commerce are significantly lower than those for NP (20% of the market vs. 80% of the market); therefore exposure to OP is generally expected to be significantly less than that of NP.

6.1 Governmental assessments of consumer exposure to NP/NPE through product use have concluded there is no cause for concern about human health effects.

As discussed previously in these comments, governmental exposure and risk assessments conducted in Canada[71] and the European Union[72] have considered exposures to NP and NPE, from their use in consumer products and concluded that these uses of NP/NPEs pose no concern for human safety.

6.2 Measured exposure of children to NP and NPE in preschool settings and the home environment is extremely low and margins of safety are extremely high.

[66] Van Miller and Staples. (2005).
[67] Environment Canada (EC). (2005, November 21).
[68] US EPA, OPPTS. (2006, July 31).
[69] OR DEQ. (2009, October).
[70] WA DoE. (2006a)
[71] EC and HC. (2001).
[72] ECB. (2002).

Attached as Appendix I to these comments is an Evaluation of Potential Exposures and Risks Associated with Environmental Media Concentrations of NP/NPE, which provide data from recent studies that monitored for NP and NPE in the household and preschool environments. While these studies do not provide product-specific data regarding content of NP or NPE in consumer products, they address the more fundamental question of exposure to children from all consumer product sources and all uses of these compounds. This assessment shows that even conservative, screening-level exposure estimates (based on worst-case aggregate exposures) are clearly acceptable, with even the upper bound Margins of Exposure (MOEs) greater than 1,000-fold above the No-Observed-Adverse-Effect-Level (NOAEL) for each route and for the aggregate exposure. These estimates are conservative for a number of reasons. The exposure estimates assume significant exposure via access to dust via dermal contact and incidental ingestion. The inhalation exposures assume extended duration exposure (up to 24 hours) at upper-bound breathing rates. The assessment concludes there is a reasonable certainty of no harm to children associated with measured environment concentrations of NP and the potential exposure pathways that may result.

7.0 SUMMARY

In summary, DoE should consider the available governmental risk assessments and the significant scientific and toxicity dataset, which are available for NP and OP. These do not support concern of human or children's health and do not support regulation of these chemicals as CHCC in Washington State according to the criteria for "high priority chemicals" as defined under Washington State RCW 70.240.010(6). Credible authorities have determined that NP and OP are not persistent, not bioaccumulative, not mutagenic or carcinogenic, and not reproductive or developmental toxicants. NP and OP have not been shown to be toxic to the nervous or immune systems. Multi-generation rat studies that have tested for potential estrogenic effects have shown that the weak estrogenic activity of NP and OP do not do not suggest concern for reproductive or developmental effects from *in utero* and\or early life stage exposures to these compounds (i.e., they do not cause adverse effects from estrogenic mechanisms at dose below maternal saturation or toxicity). Finally, governmental assessments and exposure studies further support the conclusion that NP and OP do not represent a significant exposure or risk to consumers or children. Therefore regulation of these compounds as a CHCC under draft Chapter 173-334 is not warranted. The use of available science and risk assessments to prioritize the CHCC list will save Washington State and local business community the resources to promulgate and respond to regulation under the Safe Product Reporting Rule, Chapter 173-334 on chemicals which are not intentionally used in children's products and have not been shown to be a risk to humans or children.

APE RESEARCH COUNCIL

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January 7, 2011

John R. Williams, Jr.
Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

Via email at john.williams@ecy.wa.gov.

Re: Comments on Chapter 173-334 WAC Children's Safe Products – Reporting Rule

Dear Mr. Williams:

The Alkylphenols & Ethoxylates Research Council (APERC) respectfully submits the attached comments in opposition to the inclusion of 4-Nonylphenol (CAS 104-40-5); Nonylphenol (CAS 25154-52-3); 4-NP and its isomer mixtures (CAS 84852-15-3 and CAS 25154-52-3); Phenol, 4-octyl (CAS 1806-26-4); 4-tert-Octylphenol (CAS 140-66-9); and 1,1,3,3-Tetramethyl-4-butylphenol (CAS 140-66-9) on the Reporting List of Chemicals of High Concern to Children (CHCC List) under section WAC 173-334-140 of the proposed reporting regulation.

APERC is composed of manufacturers, processors and raw material suppliers of alkylphenols and alkylphenol ethoxylates, including nonylphenol (NP) and octylphenol (OP), which are proposed to be Priority Chemicals under Chapter 173-334 . The Council has been in existence for over 25 years with the purpose of promoting the safe use of these compounds through sound science, responsible chemical management and risk-based public policy.

Please do not hesitate to contact me at blosey@regnet.com or (202) 419-1506 if I can be of further assistance, to clarify any comments or if additional information is needed.

Sincerely,

Barbara S. Losey

Barbara S. Losey
Deputy Director

Enclosures: Comments of the Alkylphenols & Ethoxylates Research Council on Washington Chapter 173-334 (01.07.2011)
Appendix I to APERC Comments (01.07.2011)

APPENDIX 1
Alkylphenols & Ethoxylates Research Council
Comments on
Washington State Children's Safe Product Reporting Rule, Chapter 173-334
Submitted January 7, 2011

Evaluation of Potential Exposures and Risks Associated with Environmental Media Concentrations of Nonylphenol and Nonylphenol Ethoxylates

Prepared by Science Strategies, Charlottesville, VA
for the
Alkylphenols & Ethoxylates Research Council, Washington, DC
October 15, 2010

The purpose of this document is to characterize potential multi-route exposures to NPE/NP based on environmental media measurements in recently published studies. The studies considered in this evaluation are summarized in Table 1. The air and dust levels of NP/NPE found in these studies are reasonably consistent.

This assessment is a screening-level evaluation of potential lower bound, most likely, and upper bound or worst case daily exposures. Our assessment considered three routes of exposure for children: dermal contact followed by absorption, inhalation, and incidental ingestion of dust following dermal contact. While inhalation is the most *likely* exposure route, in the case of children, potential dermal and incidental ingestion exposure to dust was considered.

The health risk posed by exposures to the measured NP/NPE is characterized by comparison to No-Observed-Adverse-Effect-Level (NOAEL). A variety of NOAELs have been reported for the various studies conducted on NP/NPE. Generally for NP, the most sensitive effects relate to responses due to the weak estrogenic effects of this compound with NOAELs ranging from a low of 9 mg/kg/day for accelerated vaginal opening (~2 days at 30 mg/kg/day) and increased uterine weights (+14% at 30 mg/kg/day) (Chapin, 1999), and 10 mg/kg/day (accelerated time of vaginal opening at 50 mh/kg/day) (Nagao, et al. 2001). However both of these studies were multigenerational rat studies that concluded limited effects on the reproductive system (Chapin, 1999) and reported a NOAEL of 50 mg/kg/day based on reproductive capacity (Nagao, 2001). The most sensitive toxicological endpoint reported had a NOAEL of 15 mg/kg/day (male kidney toxicity at 50 mg/kg/day)(Tyl, et al. 2006). We chose to use the most sensitive NOAEL of 9 mg/kg/day for the Margin of Exposure (MOE) calculations.

Table 2 presents exposure and risk (MOE) estimates based on the range of environmental concentrations measured in the studies listed in Table 1. The conservative, screening-level exposure estimates are clearly acceptable, with even the upper bound MOEs being greater than 1,000-fold above the NOAEL for each route and for the aggregate exposure. These estimates are conservative for a number of reasons. The exposure estimates assume significant exposure via access to dust via dermal contact and incidental ingestion. The inhalation exposures assume

extended duration exposure (up to 24 hours) at upper-bound breathing rates. Thus, there is a reasonable certainty of no harm associated with measured environment concentrations of NP and the potential exposure pathways that may result.

TABLE 1: Summary of Recent NP/NPE Exposure Studies

Reference	*Sample collection and analysis*	*Results*
Rudel RA, Dodson RE, Perovich LJ, Morello-Frosch R, Camann DE, Zuniga MM, Yau AY, Just AC, Brody JG. Environ Sci Technol. 2010 Sep 1;44(17):6583-90. Semivolatile endocrine-disrupting compounds in paired indoor and outdoor air in two northern California communities.	Sampling: Collection of paired indoor and outdoor air samples with custom-made air sampling pumps in 40 nonsmoking homes in urban, industrial Richmond, CA, and 10 in rural Bolinas, CA. Analysis: GC/MS analysis using selected ion monitoring (SIM) mode	Nonylphenol (ng/m3; n=29) outdoor air all homes: minimum: N/A maximum: 40 median: N/A Nonylphenol (ng/m3; n=20) outdoor air Richmond: minimum: N/A maximum: 40 median: N/A Nonylphenol (ng/m3; n=9) outdoor air Bolinas: minimum: N/A maximum: 39 median: N/A Nonylphenol (ng/m3; n=31) indoor air all homes: minimum: N/A maximum: 89 median: 53 Nonylphenol (ng/m3; n=21) indoor air Richmond: minimum: maximum: 89 median: 53 Nonylphenol (ng/m3; n=10) indoor air Bolinas: minimum: 26 maximum: 89 median: 49 Nonylphenol monoethoxylate (ng/m3; n=29) outdoor air all homes: minimum: N/A maximum: N/A median: N/A Nonylphenol monoethoxylate (ng/m3) outdoor air Richmond: minimum: N/A maximum: N/A median: N/A Nonylphenol monoethoxylate (ng/m3) outdoor air Bolinas: minimum: N/A maximum: N/A median: N/A Nonylphenol monoethoxylate (ng/m3; n=31) indoor air all homes: minimum: N/A maximum: 72 median: 20 Nonylphenol monoethoxylate (ng/m3; n=21) indoor air Richmond: minimum: N/A maximum: 36 median: 19 Nonylphenol monoethoxylate (ng/m3; n=10) indoor air Bolinas: minimum: 13 maximum: 72 median: 29 Nonylphenol diethoxylate (ng/m3; n=29) outdoor air all homes: minimum: N/A maximum: N/A median: N/A Nonylphenol diethoxylate (ng/m3) outdoor air Richmond: minimum: N/A maximum: N/A median: N/A

		Nonylphenol diethoxylate (ng/m3) outdoor air Bolinas: minimum: N/A maximum: N/A median: N/A Nonylphenol diethoxylate (ng/m3; n=31) indoor air all homes: minimum: N/A maximum: 18 median: N/A Nonylphenol diethoxylate (ng/m3; n=21) indoor air Richmond: minimum: N/A maximum: N/A median: N/A Nonylphenol diethoxylate (ng/m3; n=10) indoor air Bolinas: minimum: N/A maximum: 18 median: N/A
Wilson NK, Chuang JC, Morgan MK, Lordo RA, Sheldon LS. Environ Res. 2007 Jan;103(1):9-20. Epub 2006 Jun 5. An observational study of the potential exposures of preschool children to pentachlorophenol, bisphenol-A, and nonylphenol at home and daycare.	Sampling: Field sampling in NC and OH over a 48-hour period using glass cartridges with quartz fiber filter and HVS3 vacuum sampler in each child's daycare center and/or home; food, beverages, indoor air, outdoor air, house dust, soil, participants' hand surfaces and urine samples; additional samples from homes with pesticide applications within the 7 days prior to field sampling (transferable residues, food preparation surface wipes, and hard floor surface wipes); children aged 1.5 to 5 years Analysis: GC/MS analysis	Exposures and absorbed doses were not estimated for NP, because it was quantifiable in less than 11% of the samples in any medium.
Costner P, Thorpe B, McPherson A. 2005. Sick of Dust. A project of Clean Production Action.	Sampling: Dust samples from vacuum bags in ten homes in each of seven states (CA, ME, MA, MI, NY, OR, WA) Analysis: GC/MS analysis using selected ion monitoring (SIM) mode	Nonylphenol ppm (µg/g; n=7): minimum: 3.740 maximum: 10.500 mean: 5.141 Nonylphenol monoethoxylate ppm (µg/g; n=7): minimum: 3.720 maximum: 14.800 mean: 7.611 Nonylphenol diethoxylate ppm (µg/g; n=7): minimum: 5.850 maximum: 17.900 mean: 9.890 4-Octylphenol ppm (µg/g; 0/7): mnimum: <RL maximum: <RL mean: <RL Octylphenol monoethoxylate ppm (µg/g; n=7): minimum: 0.394 maximum: 3.410 mean: 1.003

		Octylphenol diethoxylate ppm (µg/g; n=7): minimum: 0.395 maximum: 8.550 mean: 1.870 4-t-methylbutylphenol ppm (µg/g; n=7): minimum: 0.154 maximum: 0.962 mean: 0.373
Wilson NK, Chuang JC, Lyu C, Menton R, Morgan MK. J Expo Anal Environ Epidemiol. 2003 May; 13(3):187-202. Aggregate exposures of nine preschool children to persistent organic pollutants at day care and at home.	Sampling: Using a URG indoor sampler (indoor/outdoor air) and High Volume Small Surface Sampler (classroom/house floor dust) in a 2-week timeframe over two 48-hour periods simultaneously at each child's day-care center and at the child's home; indoor and outdoor air, floor dust, play area soil, and duplicate diet samples, diet, hand-wipe, and urine samples; additionally household questionnaires and time–activity diaries for each child; children aged 2 to 5 years Analysis: GC/MS analysis	Nonylphenols: Results at day care centers (n=4): indoor air (ng/m3): Minimum: 165 maximum: 392 mean: 253 outdoor air (ng/m3): minimum: 0.060 maximum: 5.47 mean: 2.76 floor dust, ppm (µg/g): minimum: 4.62 maximum: 52.6 mean: 29.2 play area soil, ppm (µg/g): minimum: 0.059 maximum: 0.070 mean: 0.063 Results at homes of nine children (n=9): indoor air (ng/m3): minimum: 0.310 maximum: 402 mean: 169 outdoor air (ng/m3): minimum: 1.06 maximum: 4.36 mean: 2.42 floor dust, ppm (µg/g): minimum: 3.28 maximum: 9.62 mean: 7.22 play area soil, ppm (µg/g): minimum: 0.034 maximum: 0.162 mean: 0.076 Results at day care centers (n=4): liquid food, ppb (ng/g; n=4): minimum: 0.100 maximum: 4.32 (1/4) mean: 2.57 solid food, ppb (ng/g; n=4): minimum: 10.5 maximum: 34.2 mean: 19.9 hand wipes (ng/wipe; n=9): N/A Results at homes of nine children (n=9): liquid food, ppb (ng/g; n=9): minimum: 0.100 maximum: 3.28 (5/9) mean: 0.833 solid food, ppb (ng/g; n=9): minimum: 12.5 maximum: 76.1 mean: 32.6 hand wipes (ng/wipe): N/A Potential daily dose: calculated from the aggregate daily exposure (i.e., total weight of a pollutant to which the child is exposed daily, in ng/day, through contact with all media Estimated aggregate daily dose from homes and day care centers for nine children: potential dose (ng/kg day): maximum: 1578.793 minimum: 212.259 mean: 992.111 median: 928.738
Rudel RA, Camann DE, Spengler JD, Korn LR, Brody JG. Environ Sci Technol. 2003 Oct 15;37(20):4543-53. Phthalates, alkylphenols, pesticides, polybrominated diphenyl ethers, and other	Sampling: Urine samples from residents (breast cancer cases) and questionnaires; indoor air and house dust samples from residents' 120 homes on Cape Cod, MA using an indoor air	4-nonylphenol indoor air (ng/m3; n=120): minimum: 21 maximum: 420 median: 110 4-nonylphenol household dust (µg/g; n=118): minimum: <RL maximum: 8.68 median: 2.58 nonylphenol monoethoxylate indoor air (ng/m3; n=120):

endocrine-disrupting compounds in indoor air and dust.	pump with URG cartridges and a Eureka Mighty- Mite vacuum cleaner for collection of dust samples Analysis: GC/MS analysis using selected ion monitoring (SIM) mode; MCF-7 cell proliferation assay (E-SCREEN) of air samples	minimum: <RL maximum: 73 median: 17 nonylphenol monoethoxylate household dust (µg/g; n=118): minimum: <RL maximum: 15.6 median: 3.36 nonylphenol diethoxylate indoor air (ng/m3; n=120): minimum: <RL maximum: 26 median: <RL nonylphenol diethoxylate household dust (µg/g; n=118): minimum: <RL maximum: 49.3 median: 5.33
		nonylphenol ethoxycarboxylate indoor air (ng/m3; n=30): minimum: <RL maximum: 18 median: <RL nonylphenol ethoxycarboxylate household dust (µg/g; n=30): minimum: <RL maximum: 9.45 median: 2.12 octylphenol monoethoxylate indoor air (ng/m3; n=120): minimum: <RL maximum: 50 median: 8.6 octylphenol monoethoxylate household dust (µg/g; n=118): minimum: <RL maximum: 1.99 median: 0.13 octylphenol diethoxylate indoor air (ng/m3; n=120): minimum: <RL maximum: 120 median: <RL octylphenol diethoxylate household dust (µg/g; n=118): minimum: <RL maximum: 2.12 median: 0.306 4-octylphenol indoor air (ng/m3): N/A 4-octylphenol household dust (µg/g; n=118): minimum: <RL maximum: 0.090 Median: <RL

57

TABLE 2 Margins of Exposure for Recent Dust Studies

Exposure Route	MOE Lower Bound Exposure	MOE Most Likely Exposure	MOE Upper Bound Exposure
Dermal	602,000,000	16,700,000	4,650,000
Incidental Dust Ingestion	236,000	70,900	2,930
Inhalation	248,000	48,400	21,800
Aggregate Exposure	121,000	28,700	2,580

57
57

From: Galvin, Dave
To: Williams, John (ECY);
cc: Watson, Jay; Shield, Margaret;
Subject: Children"s Safe Products Reporting Rule comments
Date: Thursday, December 30, 2010 4:50:54 PM
Attachments: CSPA_ReportingRuleComments.pdf

John – Attached is the comment letter from the Local Ha ardous Waste Management Program in King County. Thanks for all your work on this important issue. Happy New Year. – Dave Galvin

Dave Galvin o King County Department of Natural Resources and Parks o 130 Nickerson Street, Seattle, WA 98109-1658 o (w) 206-263-3085 o (fax) 206-263-3070 o dave.galvin@kingcounty.gov o Local Hazardous Waste Management Program in King County o www.lhwmp.org

Local Hazardous Waste Management Program in King County

150 Nickerson St., Suite 100 Seattle, WA 98109-1634 www.lhwmp.org

King County Solid Waste Division

King County Water and Land Resources Division

Public Health Seattle and King County

Seattle Public Utilities

Suburban Cities Association

Participating Cities:
Algona
Auburn
Beaux Arts
Bellevue
Black Diamond
Bothell
Burien
Carnation
Clyde Hill
Covington
Des Moines
Duvall
Enumclaw
Federal Way
Hunts Point
Issaquah
Kenmore
Kent
Kirkland
Lake Forest Park
Maple Valley
Medina
Mercer Island
Newcastle
Normandy Park
North Bend
Pacific
Redmond
Renton
Sammamish
SeaTac
Shoreline
Skykomish
Snoqualmie
Tukwila
Woodinville
Yarrow Point

December 30, 2010

John R. Williams c/o
Department of Ecology
W2R HQ
PO Box 47775
Olympia WA 98540-7775

Submitted by email to: jowi461@ecy.wa.gov

RE: Comment on Children's Safe Products Act Reporting Rule – WAC 173-334

Dear Mr. Williams:

The Local Hazardous Waste Management Program in King County (Program) is a regional partnership comprised of local government agencies, including King County Water and Land Resources Division, King County Solid Waste Division, Seattle Public Utilities, Public Health – Seattle & King County, and the 37 suburban cities of King County, Washington. LHWMP provides education and technical assistance on reducing exposures to potentially harmful chemicals to childcare providers, teachers, schools, community groups, and parents. In addition to providing information and advice to local ratepayers, the Program also collects for safe disposal left-over products containing lead, mercury, cadmium and many other hazardous chemicals, at significant public expense. We welcome this opportunity to provide comments on the Children's Safe Products Act Reporting Rule.

The Program supports implementation of the Reporting Rule of the Children's Safe Products Act as a critical first step towards ensuring that products designed for children covered by this Act –which include teething devices, toys, clothing, jewelry, cosmetics, car seats, and products designed to aid in feeding or sleep- are safe and do not expose children to potentially harmful chemicals. Children are uniquely susceptible to harmful effects of chemical exposures because their bodies are still developing and their dose exposure is greater than an adult's due to their smaller body size. Improved understanding of the impacts of chemicals on young children has demonstrated health impacts at low levels of exposure, such as the case of lead where levels of lead exposure previously deemed to be safe are now known to pose significant health risks. Understanding whether toxic chemicals are present in children's products, through the comprehensive approach of the Children's Safe Products Act, is a important step towards increased consumer confidence in product safety, toward protecting the health of our children, and towards safer chemicals strategies where consumer products are designed and manufactured without the use of toxic chemicals. We appreciate the thorough process that the Department of Ecology conducted to develop this Reporting Rule and the list of Chemicals of High Concern to Children (CHCC), including convening an Advisory Group and conducting a "pilot" rule process to examine how compliance with reporting requirements would impact manufacturers of children's products.

We have the following comments on the proposed Reporting Rule – WAC 173-334.

Need for specification of public disclosure mechanism: The Introduction in WAC 173-334-010 states "The reported information will help fill a data gap that exists for both consumers and agencies." However the proposed Reporting Rule does not specify how and when the Department of Ecology will provide the reported information to the public, or to interested stakeholders such as local governments, researchers, health professionals, and caregivers for children. We strongly encourage the Department to post all Reporting Notices received from manufacturers on its web site, excluding information designated as confidential business information under state law. Such public information should be updated annually in a timely manner after each annual submission from manufacturers per Section 110.

Section 060 Revision Schedule: We support the department's planned schedule of revising the CHCC list at least every five years, and no more frequently than once every two years, to add or remove chemicals of concern. This schedule sets a practical balance between use of agency staff resources and appropriate response to new or enhanced scientific data on toxicity, exposure, and potential health impacts of chemicals. The provision allowing the directors of the departments of ecology and health to agree to take action on a specific chemical outside of that schedule is appropriate to ensure timely consideration of new information.

Section 090 Manufacturer Notice: The reporting information provided by a manufacturer to the department needs to be adequate to ensure that the children's product containing the CHCC can be specifically identified by agency staff and by consumers. 090 (b) states that the manufacturer's notice must identify "the product category or categories" in which the CHCC occurs. "Product category" is defined in Section 040 Definitions according to the GS1 Global Product Classification standard (http://www.gs1.org/gdsn/gpc) as the "brick" level for products intended for children under three years of age, and the "class" level for all other children's products. (It is our general understanding that for a toy fire truck, for example, the class would be "wheeled toys," while the related "brick" would be "truck.") This will provide general information about the type of product(s) containing the CHCC, but it does not ensure that information is specific enough to identify the product(s) with certainty. To meet the intent of the Children's Safe Products Act to provide agencies and consumers with useable information, manufacturers should be required to report the product name that the item(s) is marketed under, in addition to the product category. The federal Consumer Product Safety Commission states specific product names when it issues recalls. It seems appropriate for the state of Washington to follow this approach to provide as useful information as possible about the products of concern.

The ppm reporting ranges specified in 090 (e) seem arbitrarily selected. Setting the first ranges as 40-200 ppm and 200-1000 ppm does not provide much "fine' information about the product contents. It would be more useful to have finer gradations in the reporting ranges.

Section 120 Notice Schedule: The notice schedule defined for six categories of manufacturers by size and for four tiers of products by exposure mechanism, ranging from 1 year to 7 years, provides ample time for product manufacturers to test their products and report information to the department.

Comment on Children's Safe Products Act Reporting Rule – WAC 173-334
December 30, 2010
Page Three

This notice schedule reflects the department's sensitivity to the impacts of the reporting requirement on product manufacturers, especially small businesses. The interests of the public in obtaining adequate information about chemicals of concern in children's products under this Act must also be addressed. Therefore we do not support stretching this notice schedule out to any longer time frames.

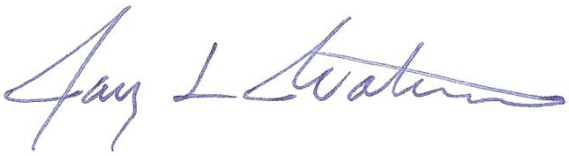
Provision 090 (5) provides an appropriate accommodation to manufacturers who are assessing safer chemical alternatives to eliminate or reduce the CHCC in their product. We hope this will serve as an incentive for children's products manufacturers to adopt an alternatives assessment strategy and redesign their products to avoid the use of CHCC's entirely.

Section 140 Reporting List of CHCCs: We recognize the practical requirement to limit the CHCC list to a manageable number of chemicals, however we look forward to future iterations of the CHCC list that more comprehensively address the large number of chemical hazards that may be present in children's products. We commend the department and its collaborators at the University of Washington for their thoughtful approach to the prioritization of chemicals on the CHCC list.

At this time, we choose to highlight one notable chemical of high concern which is omitted from the CHCC list – lead – and strongly encourage the Department to include lead on this initial CHCC list. Scientific evidence demonstrating the toxicity of lead, especially if exposures occur during fetal development or early childhood, is indisputable. A primary intent of Washington's Children's Safe Products Act (CSPA) was to address public concerns over lead found in toys and other children's products. Passage of the federal Consumer Product Safety Improvement Act (CSPIA) in July, 2008 preempted the CSPA's standard of < 90 ppm for allowable levels of lead in children's products. However the Department of Ecology has stated that the federal law did not preempt the reporting provisions of Washington's law. The CSPIA's initial standards for allowable levels of lead in products are higher than those proposed in the Children's Safe Products Act, and are phasing in over time (<600 ppm then to < 300 ppm, then eventually to < 100 ppm, but only "if feasible"). Requiring children's product manufacturers to report whether their products sold in Washington State contain lead is appropriate under Washington's CSPA, and it is important for protecting children from harmful lead exposure and creating consumer confidence in product safety.

Thank you for this opportunity to comment. Please contact Dave Galvin at 206-263-3085, dave.galvin@kingcounty.gov, if you have any questions about the comments provided.

Sincerely;



Jay L. Watson, PhD
Administrator

From: Duvall, Amy
To: Williams, John (ECY);
Subject: Comments of the American Chemistry Council on Proposed WAC 173-334
Date: Friday, December 17, 2010 3:20:18 PM
Attachments: 20101217 Final ACC Comments on Proposed WA CSPA Regs.pdf

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Hello John,

Please find attached the comments of the American Chemistry Council on Washington state's proposed WAC 173-334, regulations to implement the Children's Safe Products Act. These are the "central" ACC comments, but additional comments will be coming under separate cover from ACC Divisions and chemical-specific Panels. Please let me know if you have any uestions, and Merry Christmas

Amy

Amy L. DuVall
Director, Regulatory & Technical Affairs
American Chemistry Council
amy_duvall americanchemistry.com
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MICHAEL P. WALLS

VICE PRESIDENT

REGULATORY & TECHNICAL AFFAIRS

December 17, 2010

SENT VIA ELECTRONIC MAIL

Mr. John R. Williams
Washington State Department of Ecology
W2R HQ
P.O. Box 47775
Olympia, WA 98540-7775
jowi461@ecy.wa.gov

RE: American Chemistry Council Comments on Proposed WAC 173-334

Dear Mr. Williams:

The American Chemistry Council (ACC) appreciates the opportunity to comment on the Department of Ecologyôs (DOE or Department) WAC 173-334, proposed regulations to implement the Childrenôs Safe Products Act.[1] The safety of childrenôs products is of the utmost importance, and addressing the potential risks faced by children from possible exposure to chemicals is an important objective of the proposed regulations. Although ACC supports several concepts in the proposed regulations, there are several provisions that cause concern.

Presence Does Not Equate to Harm

ACC strongly agrees with the need to prioritize chemicals in commerce to identify those of potential concern. In the absence of prioritization, everything (or nothing) is a priority ï a result that has serious implications for the effective management of any regulatory system.

[1] ACC represents more than 140 leading companies engaged in the business of chemistry, including nearly 6,000 chemistry industry employees in Washington State. Our members apply the science of chemistry to make innovative products and services that make people's lives better, healthier, and safer. Our products are the foundation of virtually every industry, from medicines to fabrics, plastics to clean drinking water, cell phones to aircraft. ACC is committed to improved environmental, health, and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing.

In WAC 173-334-070, DOE clarifies that it will identify chemicals for inclusion in its list of chemicals of high concern to children (CHCCs) by determining whether a chemical meets both toxicity, persistence, or bioaccumulativity criteria *and* meets exposure criteria specified in the enacting legislation. ACC appreciates DOEôs recognition that the regulatory program must integrate hazard and exposure information to identify CHCCs. A robust prioritization process should utilize specific hazard and use/exposure criteria so that both governmental and industry resources are directed toward the greatest potential risks. For any chemical, natural, or synthetic, the degree of toxicity and the potential for harm is dependent upon the dose/exposure. Many government agencies, including the U.S. Environmental Protection Agency and the Centers for Disease Control readily acknowledge that the mere presence of a substanceð in our environment, in our bodies, or in our productsð does not necessarily mean there are potential exposures or the risk of harm. It is always a question of the thresholds at which there may be risk of harm, and existing risk assessment data can help fill this data need. To pave the way for a chemical reporting scheme that makes public health sense, therefore, ACC urges DOE to define ñpresence of a substanceò in the final regulations to mean presence at threshold levels.

In addition to this technical clarification, there are also communications issues that ACC requests that DOE address. ACC appreciates DOEôs accurate clarification in WAC 173-334-010 that ñ[r]eporting the presence of a CHCC does not establish that the product is harmful to human health.ò Despite this DOE admission, however, it is likely that the public will be confused as to what the CHCC list truly is, and what it is not. The proposed regulations are not clear about how and with whom the information contained in the notices will be shared. In ACCôs view, it is imperative that whenever DOE publishes or identifies the CHCC list or discusses the presence of CHCC substances in products, that DOE carefully communicate that the presence of a CHCC in a childrenôs product does not establish that a product is harmful to human health. Without communicating the CHCC list in context, the regulations will result in significant market effects for all noticed products, as consumers may understand the listing to be a regulatory decision that a product poses a risk of harm. It is inevitable that when a technical list such as the CHCC list is assembled, it will result in confusion as to what it actually means, and such confusion may unnecessarily drive safe products off Washington shelves.[2]

In short, DOE must be clear as to what the CHCC list is, and perhaps even more importantly, what it is *not*. This is essential to minimize premature product de-selection by consumers, retailers, and suppliers. Otherwise, the CHCC list becomes a blacklist by default. Under those circumstances, DOEôs proposed regulations would not serve the public health interests of the citizens of Washington state. Without plans to interpret whether these products pose real threats, the information will frighten people unnecessarily.

Along these lines, DOE may want to publicly clarify why many potentially dangerous ñtoysò have been excluded from the regulations. Section 1(3)(b) of the enacting legislation specifically excludes from the definition of ñchildrenôs productò slings and catapults, sets of darts with

[2] As Washington State Governor Christine O. Gregoire stated in her April 1, 2008 letter to the Washington House and Senate regarding the enacting legislation for WAC-173-334 (a partial veto letter), ñWithout careful implementation, this bill could adversely affect the availability of safe toys in our state, including important educational toys.ò ACC agrees.

metallic points, BB guns, pellet guns, air rifles, and pocket knives, for example. Without further clarification, the public may wrongly presume that the presence of CHCC substances in childrenôs products poses dangers that exceed those of these excluded items.

Additionally, DOE should explicitly state in its final regulations that those products already regulated under other Washington state law, or federal programs such as the Consumer Product Safety Improvement Act, Toxic Substances Control Act, Federal Insecticide Fungicide and Rodenticide Act, or by the Food and Drug Administration, for example, are not subject to DOEôs proposed regulations.

Intentional Addition to Children's Products vs. Naturally-Occurring Levels

It is unclear in both the enacting legislation and the proposed regulations whether *any* presence of a substance on the CHCC list must be reported if found to be within the identified concentration ranges, or whether only *intentional* additions of such substances are of interest. If DOE is interested in *any* presence, no matter how it came about, the Department must realize that trace contaminants may appear at levels requiring notice. ACC strongly urges DOE to clarify that its regulations apply only to intentional additions of CHCC chemicals.

ACC agrees that ñ[a] manufacturer of childrenôs products is responsible for knowing the amount of CHCCs in its childrenôs products and their componentsò (WAC 173-334-130(1)). It is possible, however, that unintentionally added ingredients (e.g., trace contaminants in public water supplies used in manufacturing or from shipping and transportation) may be able to be detected in some childrenôs products at levels above the *de minimis* levels being contemplated by DOE. Concerns regarding trace levels of contaminants arising in air, water, etc. should be the focus of appropriate environmental regulations for those media, and not these childrenôs products regulations.

***De Minimis* Level Must Be 1,000 ppm (0.1%)**

WAC 173-334-090 establishes a *de facto* minimum concentration level of 40 ppm (0.004%). ACC strongly supports DOEôs inclusion of a *de minimis* threshold, generally, but we urge DOE to set a threshold that is feasible for measurement of all potential CHCCs. We recommend 1,000 ppm (0.1%). This is a level consistent with the notification requirements established by the United Nationôs Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (*see* GHS 1.5.3.1.1 and Table 1.5.1). The GHS system has already been adopted by the United States Department of Transportation, and the level is consistent with the United States Occupational Safety & Health Administration hazard communication standards.[3] 0.1% should therefore be the smallest amount required for notice by DOE, as well. The final regulations should therefore not include WAC 173-334-090(1)(e)(i)-(ii), which contain the requirements to report ranges of equal to or more than 40 ppm but less than 200 ppm, and equal to or more than 200 ppm but less than 1,000 ppm.

[3] Additionally, a 1,000 ppm level is both technically and economically feasible.

It should be clear that the definition of a priority product includes presence of the chemical of concern above the *de minimis* level. A product containing a chemical of concern below the *de minimis* level should not be considered a priority product. For compliance and enforcement purposes, manufacturers should be expected to maintain records supporting the application of the *de minimis* threshold to their particular product.

The underlying legislation specifically states in Section 4(4) that notification is to include ñ[t]he amount of the chemical used in each unit of the product or product componentò and that ñ[t]he amount may be reported in ranges, rather than the exact amount.ò But the legislation does not prescribe what those concentration ranges are. In ACCôs view, DOE has clear legal authority to change 40 ppm to 1,000 ppm.

The legislation also bans childrenôs products or product components containing lead at more than 90 ppm and cadmium at more than 40 ppm. Additionally, it includes a possible restriction on childrenôs products or product components that contain lead at more than 40 ppm. The proposed CHCC list, however, includes far more substances than lead and cadmium. Beyond these substances, DOE has the authority to implement a *de minimis* reporting level of 1,000 ppm.

Food and Food Packaging Are Not Children's Products

Section 1(3)(a) of the legislation defines ñchildrenôs productò to include toys, childrenôs cosmetics and jewelry, child car seats, and products ñdesigned or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by childrenò. The section goes on to specifically list items that are not considered childrenôs products. Foods, food products, and food contact materials (the materials used to make food packaging) are addressed by federal statute and regulated by the federal Food and Drug Administration. They should therefore be excluded from the definition of ñchildrenôs productò.

This approach is also required by legislative intent. The Governorôs partial veto letter to the CSPA refers only to toys, car seats, and childrenôs products, as these product categories are understood by the Governor. We therefore recommend that the definition of ñchildrenôs productò expressly exempt foods and food additives (which includes food contact materials used to make food packaging) as approved by the U.S. Food and Drug Administration.

Manufacturers of Both Children's and Non-Children's Products

Clarification is needed on the tiered reporting due dates proposed in WAC 173-334-120. Specifically, when a company manufactures both childrenôs and non-childrenôs products, does it only need to consider the childrenôs products sales to determine what manufacturer category it is in? Or does DOE intend that ñannual aggregate gross salesò includes *all* products manufactured by a company, and not just childrenôs products?

Additionally, ACC strongly urges DOE to remove Product Tier 4 from proposed WAC 173-334-120(2). DOE indicates that reporting for Tier 4 (childrenôs products not intended for direct contact with the childôs skin or mouth, e.g., internal components) will be determined on a ñcase-

by-caseò basis, but it is difficult to understand what case could possibly warrant concern. Internal components are not likely to come into contact with children through reasonable and foreseeable means, and should be exempted from the reporting obligations of these regulations.

Protection of Confidential Business Information

In WAC 173-334-090(3), DOE explicitly states, ñIf a reporting party believes the information being provided is confidential business information (CBI), in whole or in part, it can request that the department treat the information as [CBI]é The department will use its established procedures to determine how it will handle the information.ò ACC commends DOE for recognizing the importance of protecting CBI and encourages the Department to do as much as it can to continue its efforts to protect American innovation and jobs by protecting legitimate CBI.

Delisting of Substances from the CHCC List

ACC commends DOE for including in its proposed regulations both a process for delisting an original CHCC substance (WAC 173-334-080), as well as intending ñto revise the CHCC list on a regular basisò (WAC 173-334-060(2)).

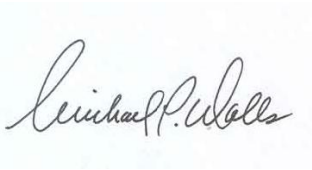
Quality of Scientific Information

The draft regulations require decisionmaking to be based on ñcredible scientific peer-reviewed information.ò WAC 173-334-070(c), 080(1)-(2). ACC supports this approach. We believe that the information relied upon by DOE must be of appropriate quality, replicable, and relevant to human health assessments. ACC therefore suggests that the phrase ñcredible scientific peer-reviewed informationò be modified to ñcredible and reliable scientific peer-reviewed literature.ò

* * * * *

We look forward to working with you and DOE on this rulemaking. If you have any questions, please contact me or Amy DuVall (amy_duvall@americanchemistry.com; 202.249.6415). Thank you in advance for considering our comments, as well as those of several ACC chemical-specific panels, which are being submitted under separate cover.

Sincerely,



Michael P. Walls
Vice President
Regulatory & Technical Affairs

From: Hentges, Steve
To: Williams, John (ECY);
Subject: Comments on Children"s Safe Products - Reporting Rule
Date: Friday, January 07, 2011 11:29:31 AM
Attachments: CSPA Reporting Rule Comments - PC-BPA Final.pdf

Dear Mr. Williams,

Please find attached comments from the Polycarbonate/BPA Global Group on the Children's Safe Products – Reporting Rule. Our comments are specifically focused on the proposed inclusion of bisphenol A in this rule.

Regards,
Steven G. Hentges, Ph.D.
Executive Director
Polycarbonate/BPA Global Group

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January 7, 2011

Mr. John R. Williams, Jr.
Department of Ecology
State of Washington
PO Box 47600
Olympia, WA 98504-7600

Submitted electronically to john.williams@ecy.wa.gov

Re: Comments on the Children's Safe Products – Reporting Rule (Chapter 173-334 WAC)

Dear Mr. Williams:

The Polycarbonate/BPA Global Group of the American Chemistry Council (ACC)[1] respectfully submits the attached comments on the Children's Safe Products – Reporting Rule (Chapter 173-334 WAC). The Polycarbonate/BPA Global Group represents the leading global manufacturers of bisphenol A (BPA) and polycarbonate plastic. For many years the group has sponsored scientific research to understand whether bisphenol A has the potential to cause health or environmental effects and to support scientifically sound policy.

These comments, focused on the inclusion of bisphenol A on the list of chemicals of high concern to children, are complementary to general comments from ACC on the proposed rule that have been submitted separately. As described in our attached comments, bisphenol A does not clearly meet the Children's Safe Products Act (CSPA) standard as a High Priority Chemical and should not otherwise be considered as a high priority for action under CSPA.

[1] The American Chemistry Council represents the leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The Council is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $435 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other business sector.

Please do not hesitate to contact me if I can be of further assistance to clarify any comments or if additional information is needed. I can be reached at (202) 249-6624 or by e-mail at steve_hentges@americanchemistry.com.

Regards,

Steven G. Hentges, Ph.D.
Polycarbonate/BPA Global Group

Attachment

Comments of the Polycarbonate/BPA Global Group on the State of Washington's Proposed Children's Safe Products – Reporting Rule

January 7, 2011

1. Bisphenol A is Not a High Priority for Washington's Children's Safe Products Reporting Rule

As described in a series of reports from the Department of Ecology (Ecology), it is a significant challenge to screen through the many chemicals in commerce and determine which ones are high priority chemicals of high concern for children (CHCC), as defined by the Children's Safe Products Act (CSPA). In a multi-phase, systematic and well-documented approach, Ecology has attempted to identify the highest priority chemicals for this first reporting rule. However, an inherent feature of the approach taken by Ecology is that the focus will necessarily be on chemicals with extensive data, which is not necessarily the same as highest priority for children's health.

In addition, by selecting chemicals based primarily on the existence of hazard data, Ecology is not taking full advantage of extensive information in the form of risk assessments that is highly relevant to the safety of children's products. In this regard, Ecology's approach does not go far enough and could result in selection of chemicals that have already been thoroughly evaluated by other credible government agencies. Although risk assessment is outside the scope of CSPA and may be beyond Ecology's resources, Ecology has acknowledged the importance and value of risk assessment. There is no reason why Ecology should not use the results of existing risk assessments to at least set priorities for the reporting rule.

Overall, the approach taken by Ecology may result in undue attention to well-studied chemicals rather than to chemicals of highest priority for children's health. This will limit the value of information collected with the reporting rule.

As discussed in detail in the following sections, bisphenol A should not be a high priority for the Children's Safe Products Reporting Rule because:

- Bisphenol A is Present in Polycarbonate Plastic and Epoxy Resins Only as a Trace Level Impurity
- Bisphenol A Does Not Clearly Meet the Children's Safe Products Act Standard for a "High Priority Chemical"
- Multiple Risk Assessments Support the Safety of Bisphenol A
- Focus on Bisphenol A May Be Counterproductive to the Broader Interest in the Safety of Children's Products

2. Bisphenol A is Present in Polycarbonate Plastic and Epoxy Resins Only as a Trace Level Impurity

Bisphenol A is an industrial chemical that is primarily used to manufacture polycarbonate plastic and epoxy resins. In both cases, bisphenol A is a raw material that undergoes a chemical reaction with one or more other chemicals to produce the plastic or resin. In addition, epoxy resins are further mixed with additional chemicals and undergo a second chemical reaction, which "cures" or crosslinks the resin, at the point of use to form a finished product, for example a coating on a metal surface.

As a result of the chemical reactions that form polycarbonate plastic and epoxy resins, these materials, as sold in finished form, contain only trace levels of residual bisphenol A as an impurity. The level of bisphenol A carried over to consumer products as an impurity from these materials is typically in the low part per million range. It is not intentionally added to the finished materials or consumer products made from these materials and, as a trace level impurity, it provides no functional purpose.

Polycarbonate plastic is a clear, lightweight, highly shatter-resistant material that is used in a wide range of consumer products that require these beneficial properties. It is known as a thermoplastic since it can be heated and molded to form a finished article. Polycarbonate plastic is used, for example, in products ranging from eyeglass lenses, sports safety equipment, security shielding, components of life-saving medical devices, electronic equipment housing, construction glazing, and automotive components. It can also be used to make various products that contact food and beverages.

Epoxy resins are known as thermosetting resins since they are "cured" by reaction with a "hardener" into a high strength, chemically resistant material with good adhesion to various substrates. They are commonly used as protective coatings or adhesives in both industrial and consumer products. Common examples include corrosion-resistant coatings for structural steel, automobile primer coatings, industrial flooring, and the resin matrix in fiber reinforced composite applications. Epoxy resins are almost universally used as the protective coating in most food and beverage cans where they provide a significant public health benefit by preventing corrosion, which can result in contamination of food with metals and microbial infiltration if the integrity of the can is breached. Since epoxy resins have good thermal and hydrolytic resistance, they enable high temperature sterilization of canned foods, thus preventing food borne illnesses.

Bisphenol A, polycarbonate plastic, and epoxy resins have been produced commercially for more than 50 years. Over this time, bisphenol A has become one of the best tested of all substances in commerce. As discussed below, the safety of these materials has been vetted repeatedly and recently by numerous government agencies around the world. The consensus of these government bodies is that bisphenol A is not a risk to human health, including the health of infants and children.

3. Bisphenol A Does Not Clearly Meet the Children's Safe Products Act Standard for a "High Priority Chemical"

As outlined in the Children's Safe Products Act (CSPA), designation as a high priority chemical of high concern for children (CHCC) requires that a chemical must meet the definition of a high priority chemical [RCW 70.240.010(6)[1]] and must either be found in humans or have a potential exposure route to children [RCW 70.240.030]. Of particular relevance for bisphenol A is the requirement that a chemical may be designated as a high priority only if it has been "identified … on the basis of credible scientific evidence as known to do one or more" of the listed toxic effects or characteristics (emphasis added). This definition is the regulatory standard that must be met to designate a chemical as a high priority.

The Department of Ecology's extensive documentation thoroughly describes a systematic, multi-phase process to screen through the many thousands of chemicals in commerce and identify those that meet the criteria as CHCCs. The three primary phases are characterized in Ecology's reports as:

- Phase 1 – Building or Identifying Potential CHCCs
- Phase 2 – Prioritization
- Phase 3 – Vetting

In Phase 1, Ecology appropriately relied on readily available information to develop an initial list of potential CHCCs. The information was not critically evaluated at this stage to confirm that the CSPA regulatory standard for designation as a high priority chemical had been met.

Phase 2 focused on prioritization of chemicals on the initial list. Although additional information was used to facilitate prioritization, confirmation that the CSPA regulatory standard had been met was not explicitly a part of Phase 2. A limitation of Phase 2 is that much of the information used was in the form of "Categories" assigned by other agencies to characterize different forms of toxicity (e.g., categories assigned under the EU Classification and Labeling Directive to characterize different types of carcinogens or reproductive toxicants).

Only Phase 3 had the explicit goal of ensuring that the regulatory standard for designation as a high priority chemical had been met. This took the form of an error check on the information used in Phase 2, but it is not apparent that the information was evaluated in detail in comparison

[1] "High priority chemical" means a chemical identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative by the department on the basis of credible scientific evidence as known to do one or more of the following:

(a) Harm the normal development of a fetus or child or cause other developmental toxicity;
(b) Cause cancer, genetic damage, or reproductive harm;
(c) Disrupt the endocrine system;
(d) Damage the nervous system, immune system, or organs or cause other systemic toxicity;
(e) Be persistent, bioaccumulative, and toxic; or
(f) Be very persistent and very bioaccumulative.

to the regulatory standard. In particular, it is not apparent that the scientific data underlying the various category characterizations was reviewed to determine if it supported a conclusion that a chemical has been identified "as known to" cause any of the listed toxic effects.

As described in detail below, we believe that the information used in Phases 1-3 does not clearly support a conclusion that bisphenol A is "known to do one or more" of the toxic effects listed in the definition of high priority chemicals. In the following sections, the information used for bisphenol A in each phase is described and analyzed in detail versus that regulatory standard.

A. The European Commission has not identified bisphenol A "as known to" disrupt the endocrine system

One of the information sources used in Phase 1 to identify bisphenol A as a potential CHCC is the European Commission Communication on a Community Strategy for Endocrine Disruptors." This document was published by the European Commission in December 1999 with the full title below.[2]

> "*Community Strategy for Endocrine Disruptors – a range of substances suspected of interfering with the hormone systems of humans and wildlife*" (emphasis added)

As indicated by the title, this document discusses a strategy to address the subject of endocrine disruption and does not list or characterize specific chemicals. With few exceptions the document does not even mention specific chemicals and, in particular, does not mention bisphenol A.

Importantly, the title and document consistently refer to substances suspected of being endocrine disrupters, not substances identified "as known to" disrupt the endocrine system. A key reason for the consistent use of "suspected" as a qualifier is that the strategy document extensively focuses on the need for further research and evaluation to identify and assess suspected endocrine disruptors. A significant part of the strategy outlined in this document consists of numerous recommendations and actions for further research and evaluation.

> "Lists of suspected ED chemicals have been drawn up by various organisations on the basis of available information. However, further scientific data collection and research is necessary to identify the selection criteria used to place substances on these lists."[3]

A key short-term action item identified in the strategy document was to establish a list of substances to prioritize for further evaluation.

> *"Establishment of a priority list of substances for further evaluation of their role in endocrine disruption*

[2] Communication from the Commission to the Council and the European Parliament, Community Strategy for Endocrine Disrupters, December 17, 1999, (http://ec.europa.eu/environment/endocrine/documents/comm1999_en.htm).

[3] *Id*. at p. 9.

> The Commission intends to establish a priority list of substances for further evaluation of their role in endocrine disruption, hereinafter referred to as the "ED priority list"."[4]

This action item was initially implemented through a report prepared by consultants that compiled a candidate list of 564 substances from review of other lists and sources of information.[5] These substances were subjected to a preliminary evaluation for the purpose of sorting them into categories to set priorities for additional testing and evaluation. It is through this preliminary evaluation that bisphenol A was categorized as a Category 1 substance.

This categorization is not a conclusion that bisphenol A is an endocrine disruptor but only indicates priority for further evaluation. In this regard, it should be noted that the legend section in Appendix 10a of Ecology's Phase 1 report incorrectly refers to Category 1 as "probable," presumably intending to mean that Category 1 substances are probable endocrine disruptors. However, this characterization is incorrect since the term "probable" is not used in the report or the definition for Category 1.[6]

In a subsequent European Commission report on the implementation of the strategy outlined earlier, the point is clearly made that the priority list is preliminary and intended to provide a basis for gathering and evaluating further data.[7]

> "The preliminary priority list of substances for further evaluation is not a negative list of substances but it is meant to provide a basis for gathering further data on endocrine disrupting effects of those substances and for their subsequent evaluation."

Consistent with a main thrust of the European Commission strategy document, it is clear from the concluding recommendations in the consultant report that further research and evaluation was needed. Recommendations of particular relevance to bisphenol A and other Category 1 substances are listed below.[5]

> *"Recommendation 1: A follow-up has to be made to further evaluate the substances on the candidate list of 553 chemicals."*
>
> …
>
> "At present there is no consensus yet on the methodology to assess endocrine disrupting effects."
>
> …

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[4] *Id*. at p. 15-16, Short-term action.

[5] *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting*, Final Report, BKH Consulting Engineers, Delft, The Netherlands in association with TNO Nutrition and Food Research, Zeist, The Netherlands, June 21, 2000 (http://ec.europa.eu/environment/docum/pdf/bkh_main.pdf).

[6] *Id*. at p. 11. Category 1 is defined as "At least one study providing evidence of endocrine disruption in an intact organism. Not a formal weight of evidence approach."

[7] *Commission Staff Working Document on the implementation of the "Community Strategy for Endocrine Disrupters" - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706), (COM (2001) 262) and (SEC (2004) 1372)*, November 11, 2007 (http://ec.europa.eu/environment/endocrine/documents/sec_2007_1635_en.htm).

"Recommendation 3: Standard tests have to be developed to identify endocrine disrupters

Recommendation 4: These tests should be applied with priority to category 1 substances with evidence of endocrine disrupting activity. Risk assessments will also need to be reconsidered when agreed test methods become available."

These recommendations are consistent with the European Commission strategy document, which indicated that the priority list was to be used for several purposes including the two below.[4]

"The priority list will be used, inter-alia:

- to identify substances for 'priority' testing once agreed test methods become available,
- to identify substances which can be, or already being addressed, under existing Community legislation covering hazard identification, risk assessment and risk management"

The second purpose is of particular relevance for bisphenol A since a comprehensive risk assessment of bisphenol A had already been initiated under the European Existing Substances Regulation. Because this activity was underway and substantively met the goal of the European endocrine disruptor strategy, bisphenol A was not further discussed in the context of the endocrine disruptor strategy.

In the following years, a comprehensive risk assessment on bisphenol A was published in 2003 and a fully updated risk assessment was published in 2008.[8] These assessments confirm that bisphenol A does not pose a risk to the general public, including infants and children, from all current sources of exposure, including use of polycarbonate plastic and epoxy resins in consumer products. The assessments extensively focused on the potential for bisphenol A to cause health (or environmental) effects through endocrine-mediated pathways. Of particular relevance for CSPA, the assessments did not identify bisphenol A "as known to" disrupt the endocrine system.

It is clear from the record, as summarized above, that the European Commission has not identified bisphenol A "as known to" disrupt the endocrine system. The consultant report that initially categorized bisphenol A is not an authoritative governmental entity and, in any case, only produced a candidate list of substances for priority setting purposes. Subsequent activities, in particular a comprehensive European Union risk assessment, concluded that bisphenol A does not pose a risk to human health, including the health of infants and children, and did not reach a conclusion that identified bisphenol A "as known " disrupt the endocrine system.

[8] The updated risk assessment, which includes a summary of the preceding risk assessment, is available at http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/ADDENDUM/bisphenola_add_325.pdf.

B. The National Toxicology Program Center for the Evaluation of Risks to Human Reproduction has not identified bisphenol A "as known to" cause reproductive or developmental harm

A second information source used in Phase 1 to identify bisphenol A as a potential CHCC is the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR). This citation refers to a report published in 2008 by the National Toxicology Program, which included an underlying comprehensive report that was prepared by an expert panel.[9]

The NTP-CERHR report on bisphenol "presents the NTP's opinion on the potential for exposure to bisphenol A to cause adverse reproductive or developmental effects in people."[10] To reach their conclusions, NTP and their expert panel review relevant scientific literature including human studies, laboratory animal studies, and exposure information. For bisphenol A, the review extensively focused on the potential for bisphenol A to cause reproductive or developmental effects through endocrine-mediated mechanisms.

The overall conclusions in NTP-CERHR reports are expressed on a qualitative five-point scale ranging from serious concern, concern, some concern, minimal concern, and negligible concern for adverse effects. For bisphenol A, the NTP-CERHR report did not reach any conclusions at the top two concern levels. The full range of conclusions from the NTP-CERHR report on bisphenol A are presented below.[11]

> "The NTP has *some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A.
>
> The NTP has *minimal concern* for effects on the mammary gland and an earlier age for puberty for females in fetuses, infants, and children at current human exposures to bisphenol A.
>
> The NTP has *negligible concern* that exposure of pregnant women to bisphenol A will result in fetal or neonatal mortality, birth defects, or reduced birth weight and growth in their offspring.
>
> The NTP has *negligible concern* that exposure to bisphenol A will cause reproductive effects in non-occupationally exposed adults and *minimal concern* for workers exposed to higher levels in occupational settings."

The meaning of these concern level conclusions is readily apparent from the text of the NTP-CERHR report. In general, NTP-CERHR noted that "evidence from the limited number of

[9] NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A, September 2008 (http://cerhr.niehs.nih.gov/evals/bisphenol/bisphenol.pdf).

[10] *Id*. at p. ix.

[11] *Id*. at p. 38-39.

studies in humans exposed to bisphenol A is not sufficient to reach conclusions regarding possible developmental or reproductive hazards."[12]

Accordingly, rather than human studies, the "some concern" and "minimal concern" conclusions are both based on certain studies that report effects in laboratory animals after low level exposure to bisphenol A. Importantly though, for both the "some concern" and "minimal concern" conclusions, NTP-CERHR noted that "These studies in laboratory animals provide only limited evidence for adverse effects on development and more research is needed to better understand their implications for human health" (emphasis added).

The limited nature of these conclusions is further supported by a section of the report that asks and answers the question "Can bisphenol A affect human reproduction and development?"[13] The answer to this question is not "Yes" or even "Probably", but only "Possibly," for the same reasons discussed above that support the concern level conclusions.

Overall, the conclusions of the NTP-CERHR report do not indicate that bisphenol A has been identified "as known to" cause reproductive harm or harm the normal development of a fetus or child or cause other developmental toxicity. Rather, the conclusions indicate that more research is needed in certain areas to better understand whether bisphenol A is a human health concern. Indeed, the FDA Commissioner, Margaret Hamburg, in referencing the NTP-CERHR report said "'Some concern' means that we need to know more."[14]

It is notable that the NTP-CERHR report on bisphenol A, along with other available scientific information, was reviewed under the requirements of California's Proposition 65,[15] which requires the state to publish a list of chemicals known to cause birth defects or other reproductive or developmental harm.[16] The primary mechanism for adding chemicals to this list is when an independent committee of scientists and health professionals finds that a chemical has been "clearly shown" to cause birth defects or other reproductive harm. The members of the committee, known as the Developmental and Reproductive Toxicant Identification Committee (DART IC), are appointed by the Governor and are designated as the "State's Qualified Experts" for evaluating chemicals under Proposition 65. When determining whether a chemical should be placed on the list, the committee bases their decision on the most current scientific information available.

In July 2009, the DART IC reviewed all relevant scientific studies on bisphenol A, principally including the NTP-CERHR report, and voted unanimously that bisphenol A has not been clearly shown to be a reproductive or developmental toxicant. This recent conclusion, which is consistent with the views of other government agencies that have reviewed bisphenol A,

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[12] *Id*. at p. 9.

[13] *Id*. at p. 6-7.

[14] Nature News, 21 January 2010, http://www.nature.com/news/2010/100120/full/463274a.html

[15] The complete title for Proposition 65 is the Safe Drinking Water and Toxic Enforcement Act of 1986.

[16] Although not relevant for bisphenol A, Proposition 65 also includes chemicals that cause cancer.

confirms that bisphenol A has not been identified "as known to" cause reproductive harm or harm the normal development of a fetus or child or cause other developmental toxicity.

C. The EPA Integrated Risk Information System has not identified bisphenol A "as known to" cause health effects listed in the Children's Safe Products Act

The third information source used in Phase 1 to identify bisphenol A as a potential CHCC is the EPA Integrated Risk Information System (IRIS). In particular, the legend section in Appendix 10a of Ecology's Phase 1 report indicates that bisphenol A (and many other substances) were "identified due to RfD." Presumably this means that the selection criterion was the existence of a Reference Dose (RfD) in IRIS. As defined by EPA, an RfD is "An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." In simple terms, an RfD is a safe exposure level that is unlikely to cause health effects.

The RfD for bisphenol A was derived from an NTP carcinogenesis study that found no convincing evidence that bisphenol A causes cancer. The RfD was based not on a carcinogenic effect (or any other toxic effect), but rather on reduced body weight that was associated with the very high doses used in this study. Reduced body weight is routinely observed for many chemicals at high doses, and studies conducted according to internationally accepted guidelines generally require that a high dose exhibiting an overt effect be included in the study to confirm that the dose range studied has reached the maximum tolerated dose. High dose effects on body weight are not a suitable selection criterion for CSPA since essentially any chemical would qualify as a high priority chemical.

Overall, the IRIS database does not indicate that bisphenol A has been identified "as known to" cause any of the health effects identified in CSPA. However, it should be noted that the IRIS database for bisphenol A is not up-to-date and is not the most appropriate source of information either to include or exclude bisphenol A from further consideration.

D. The weight of evidence for bisphenol A evaluated in Phase 2 does not meet the Children's Safe Products Act standard for a "high priority chemical"

As summarized in the score sheets, chemicals identified in Phase 1 were prioritized using a framework intended to "qualitatively evaluate the evidence for toxicity and potential for exposure … based upon a weight-of-evidence approach." For Phase 2, most of the toxicity data is presented in the form of "Categories" assigned by other agencies to characterize different forms of toxicity. To designate priorities, these characterizations were further categorized as Worst, Severe, Bad, No, or No Information. Although described as a weight-of-evidence approach, it's not apparent how the evidence was weighed or, more importantly, whether the scientific data underlying the various category characterizations was reviewed and weighed to determine if it supported a conclusion that a chemical has been identified "as known to" cause any of the toxic effects listed in CSPA. From the score sheets and associated documentation, it

would appear that the categories Worst, Severe, and Bad are all considered to meet the "as known to" standard.

The single piece of evidence that led to the "Final Toxicity Determination" of Worst for bisphenol A is the European Commission endocrine disruptor program that was also used in Phase 1. However, as extensively discussed above, the European Commission has not identified bisphenol A "as known to" disrupt the endocrine system. Regardless of how Ecology may choose to characterize the outcome of the European program, what matters is whether that outcome meets the CSPA regulatory standard. From the extensive record on the European program, the outcome for bisphenol A certainly does not meet that standard.

For toxicity, the piece of evidence that led to the "Final Developmental or Reproductive Determination" of Severe is the NTP-CERHR report on bisphenol A, which also was used in Phase 1. As discussed above in detail, the conclusions of the NTP-CERHR report do not indicate that bisphenol A has been identified "as known to" cause reproductive or developmental harm. Again in this case, although Ecology may choose to characterize the outcome of the NTP-CERHR evaluation as Severe, the extensive record from the NTP-CERHR report indicates that bisphenol A does not meet the CSPA regulatory standard.

It is also notable that the California Proposition 65 line in the bisphenol A score sheet is marked as No Information. Although it is correct that bisphenol A is not listed as a reproductive or developmental toxicant under Proposition 65, this is quite different from an absence of information. As described above in regard to the NTP-CERHR report, California's expert committee (DARTIC) reviewed all relevant scientific studies on bisphenol A, principally including the NTP-CERHR report, and voted unanimously in July 2009 that bisphenol A has not been "clearly shown" to be a reproductive or developmental toxicant. Rather than No Information, this outcome is very important information since it confirms that the NTP-CERHR report did not identify bisphenol A as a reproductive or developmental toxicant under California's "clearly shown" standard, which is comparable to the CSPA "as known to" standard.

Two other lines in the bisphenol A score sheet are also noteworthy in regard to the CSPA regulatory standard. The third line item indicates that bisphenol A is a Category 3 reproductive toxicant in reference to "EU Existing Substances" and a Category 2 reproductive toxicant in reference to "GHS." As an aside, the reference to EU Existing Substances is apparently mistaken and should refer to a different EU regulation on classification and labeling. Note, however, that very relevant information in reference to the EU Existing Substances Regulation will be discussed further below.

In spite of the different numbers, the Category 2 and Category 3 characterizations are equivalent and have essentially the same meaning. The Globally Harmonized System (GHS), using the Category 2 notation, has replaced the now outdated EU regulation on classification and labeling, which used the Category 3 notation. What is important though is not the numbers, but the meaning of the characterizations compared to the CSPA regulatory standard. According to

GHS, Category 2 means a "suspected" reproductive toxicant, and the now outdated Category 3 meant a "possible" reproductive or developmental toxicant. Although Ecology may characterize these categories as Bad, it is apparent from the use of the qualifiers "suspected" and "possible" that they do not meet the CSPA "as known to" regulatory standard.

Overall, the information used in Phase 2 does not clearly indicate that bisphenol A meets the regulatory standard to be designated as a high priority chemical. As described in the next section, better information that is well-suited for Ecology's purpose with CSPA is available and should be used to assess and prioritize bisphenol A.

4. Multiple Risk Assessments Support the Safety of Bisphenol A

A. Risk assessment is an invaluable tool that should be used to the fullest extent possible to set priorities and assess safety

As noted by Ecology, "Risk assessment is a valuable tool that manufacturers and regulators can use to evaluate the risk of a specific chemical in a specific product." In spite of the recognized high value of risk assessments, Ecology has also stated "It is not our intent to conduct risk assessments of each product; nor does the law require this. It is beyond our current and foreseeable resources to determine if every individual product is 'safe.'" While it may be reasonable from a resource perspective not to conduct a risk assessment in each case, it is difficult to justify ignoring such credible work that has already been conducted, and there is no apparent reason why Ecology should not rely heavily on credible risk assessments that have already been conducted by other government agencies.

As stated by Ecology at the outset in Phase 1, "with only limited resources to put toward this effort, we knew we would need to build upon the work of others." As further noted in the report from the Department of Health on their Phase 3 work, "The strongest sources of developmental and reproductive toxicity information used in Phase 2 were NTP-CERHR evaluations and the EU Existing Substances risk assessments." Nevertheless, the very extensive work of these and many other government entities worldwide has largely been ignored rather than built upon.

Two examples have been briefly discussed above in regard to the Phase 1 and 2 evaluations of bisphenol A. Most notably, the European Union published a comprehensive risk assessment on bisphenol A in 2003 and a fully updated risk assessment was published in 2008.[8] These risk assessments were conducted under the EU Existing Substances Regulation, which was mistakenly cited in the Phase 2 score sheet as the source of the Category 3 reproductive toxicity characterization. Far more important than that characterization, these assessments confirm that bisphenol A does not pose a risk to the general public, including infants and children, from all current sources of exposure, including use of polycarbonate plastic and epoxy resins in consumer products.

Although not a complete risk assessment, a second example that is very relevant is the recent review of bisphenol A under California's Proposition 65, which was conducted by California's expert committee (DARTIC). This review of the science provides strong support for the conclusion that bisphenol A is not "known to" cause reproductive or developmental harm.

These are only two examples, but are particularly striking in light of Governor Gregoire's remarks in her April 1, 2008 partial veto message on Engrossed Second Substitute House Bill 2647. Consistent with what Ecology has stated about building upon the work of others, Governor Gregoire stated "The Department should rely on safety testing conducted in the European Union and California, to the extent they provide a reasonable assurance of safety, in order to help establish a degree of consistency for the industry." The European Union risk assessments and the California Proposition 65 review do provide a reasonable assurance of safety and should be used by Ecology, along with other assessments discussed below, to set priorities.

B. Government entities worldwide support the safety of bisphenol A in consumer products

As noted above, bisphenol A is one of the best tested of all substances in commerce. In addition to the EU risk assessment and the assessment of bisphenol A under California's Proposition 65, the extensive scientific database on bisphenol A has been comprehensively reviewed by many other government entities around the world, in particular in the last few years. These government entities have all determined, based on the science, that bisphenol A is safe for use in food contact and other consumer products. A recent summary of these government assessments is attached.

Since the attached summary was last updated, the European Food Safety Authority (EFSA) announced the conclusions of their updated assessment in September 2010. The assessment was conducted by a panel of more than 20 independent scientific experts from throughout Europe, and included consultation with other government agencies worldwide. More than 800 new studies published since the previous EFSA assessment were reviewed by the expert panel. As stated in their report, "<u>based on this comprehensive evaluation of recent toxicity data, the Panel … concluded that no new study could be identified, which would call for a revision of the current TDI</u> [Tolerable Daily Intake]"[17] (emphasis added). EFSA's conclusion applies to all age groups, including infants and children, which makes it highly relevant to CSPA.

The EFSA expert panel evaluated in detail a large number of studies that examined the potential for bisphenol A to cause reproductive or developmental toxicity. Summary comments on these studies are shown below:

> "The CEF Panel members acknowledge that some recent studies report adverse effects on animals exposed to BPA during development at doses well below those used to determine the current TDI. … However, <u>these studies have many shortcomings. At present the</u>

[17] The full EFSA report is available at http://www.efsa.europa.eu/en/scdocs/scdoc/1829.htm.

relevance of these findings for human health cannot be assessed…" (EFSA) (emphasis added)

Similar to NTP-CERHR, which found "only limited evidence for adverse effects on development and more research is needed to better understand their implications for human health" (emphasis added), the EFSA conclusions do not clearly identify bisphenol A "as known to" cause reproductive or developmental harm.

Taken together, the many scientific assessments of bisphenol A strongly support the conclusion that bisphenol A is safe for use in food contact and other consumer products. These assessments also confirm that bisphenol A does not meet the CSPA regulatory standard as a "high priority chemical" and should not be considered by Ecology as a high priority for the proposed reporting rule.

5. Focus on Bisphenol A May Be Counterproductive to the Broader Interest in the Safety of Children's Products

As plainly indicated by its title, CSPA is aimed at the safety of children's products. In particular, CSPA is focused on one aspect of children's product safety, specifically potential harm from the presence of toxic chemicals in children's products. Conversely though, CSPA does not comprehensively address all aspects of children's product safety. Nevertheless, in setting priorities for CSPA, Ecology should be cognizant of the potential for unintended consequences that may be counterproductive to the broader interest in the safety of children's products.

A. Polycarbonate plastic and epoxy resins are used to enhance safety

As discussed above, bisphenol A is primarily used to make polycarbonate plastic and epoxy resins. These materials are used in a wide range of consumer products, including some products that may fall under the jurisdiction of CSPA, because of their superior performance attributes. Of particular relevance for children's products are the safety attributes of these materials.

A key performance attribute of polycarbonate plastic that makes it of high value in consumer products is its shatter-resistance. To the extent that polycarbonate plastic is used in children's products such as bicycle helmets, safety glasses or certain toys, it is used to take advantage of this key attribute, which enhances the safety of the product. Epoxy resins are chemically resistant and durable materials that are used as coatings or adhesives in a wide range of applications. As with polycarbonate plastic, epoxy resins are used in consumer products because of their performance attributes, which contribute to the safety of the product.

Although CSPA does not directly restrict the use of these materials in consumer products, Ecology must recognize that the CSPA reporting requirements are a burden to children's product manufacturers and a deterrent to the use of these materials. As an unintended consequence, consumer product manufacturers will have an incentive to use alternative materials that are not

subject to reporting. However, since polycarbonate plastic and epoxy resins are used because of their superior performance attributes, alternative materials may not have equivalent performance (e.g., may have inferior shatter-resistance), which may result in products that are less safe overall.

Ecology must balance these concerns with the value of the information that would be gained by including bisphenol A in the current reporting rule. Considering that bisphenol A is one of the best tested and among the most thoroughly assessed substances in commerce, and in light of the outcomes of those assessments by regulatory agencies worldwide, it seems unlikely that any information of comparable importance could be gathered from the reporting rule. In contrast, the reporting rule will encourage the use of alternatives that almost certainly have not been tested as comprehensively and have not been reviewed so thoroughly by regulatory agencies.

B. The Reporting Rule Should Exclude Consumer Products Comprehensively Regulated by FDA

It appears from the language of CSPA and the specific products mentioned that the intent of CSPA is to focus on children's products such as toys, cosmetics and jewelry. Although not specifically mentioned, products such as food and drugs are presumably not included within the scope of CSPA or the reporting rule. As part of the reporting rule, Ecology should make it clear that products comprehensively regulated by FDA are not included within the scope of the reporting rule.

In particular, FDA comprehensively regulates foods, food additives, drugs and medical devices. Included within the scope of FDA-regulated food additives are food packaging (e.g., metal food and beverage cans) and reusable food and beverage containers (e.g., baby bottles, water bottles, cups). Both polycarbonate plastic and epoxy resins are used in FDA-regulated food contact products because of their superior performance attributes and Ecology should avoid creating any disincentive to continue using these materials. Furthermore, since Washington has legislatively banned baby bottles and sippy cups containing bisphenol A, including such products within the scope of the reporting rule would not result in any useful information.

85

GOVERNMENT AND INDEPENDENT SCIENTIFIC ASSESSMENTS

United States

- **U.S. Food and Drug Administration (FDA) and Department of Health and Human Services (HHS)** – In January 2010, FDA and HHS reaffirmed that "*BPA is not proven to harm children or adults*."

  As stated by FDA: "*Studies employing standardized toxicity tests have thus far supported the safety of current low levels of human exposure to BPA.*" As further noted by Dr. Joshua Sharfstein of FDA: "*If we thought it was unsafe, we would be taking strong regulatory action.*"

  In recognition of some concern related to effects reported in certain recent studies, FDA is carrying out in-depth studies in conjunction with the National Toxicology Program to answer key questions and clarify uncertainties. In the interim, FDA is taking reasonable steps to reduce human exposure to BPA in the food supply and stated:

  > "*Given that these are preliminary steps being taken as a precaution, it is important that no harmful changes be made in food packaging or consumption, whether by industry or consumers, that could jeopardize either food safety or reduce access to and intake of food needed to provide good nutrition, particularly for infants.*"

- **U.S. Environmental Protection Agency (EPA)** – In March 2010, EPA released an "action plan" on BPA that outlines EPA's review of BPA and their plans for follow-up actions. Notably, EPA did not propose any actions, regulatory or otherwise, regarding human health but will continue to coordinate closely with FDA, CDC and NIEHS.

- **U.S. National Toxicology Program (NTP)** – The September 2008 NTP final report on the potential for BPA to affect human reproduction or development found no direct evidence for health effects in people. It also confirmed that human exposure to BPA is very low.

  On a standard five-level scale ranging from 'serious concern' to 'negligible concern,' NTP reported no concerns for any age group at the top two levels and only negligible concern for adults. Based on what NTP characterized as limited and inconclusive evidence from laboratory animal studies, NTP expressed 'some concern' regarding effects on the brain, behavior, and the prostate gland but noted that additional research is needed to better understand whether these findings are of any human health significance. The NTP report is designed to serve as a resource to regulatory agencies and has specifically been considered in FDA's ongoing safety assessment.

- **California Proposition 65** – 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. That law can require warnings when listed substances are present in consumer products. The panel's decision was based on their own review of the scientific evidence on BPA, including their assessment of the NTP report.

- **NSF International** (a not-for-profit public health and safety organization) – In February 2008, NSF published its comprehensive safety assessment of BPA and set a safe intake level for BPA in drinking water. That level is comparable to the level established by the European Food Safety Authority for BPA in food. The assessment was led by Dr. Calvin Willhite, a respected scientist with the California Department of Toxic Substances Control.

- In October 2008, an **expert scientific panel,** convened by **Gradient Corporation**, published the results of its weight-of-the-evidence evaluation of low-dose reproductive and developmental effects of BPA. This evaluation is the third in a series that began with an evaluation, published in 2004, by an independent panel of scientific experts organized by the **Harvard Center for Risk Analysis**. Based on its review of scientific literature available through July 2008, the panel concluded: "*The weight of evidence does not support the hypothesis that low oral doses of BPA adversely affect human reproductive and developmental health.*"

85

Canada

- **Health Canada** – In October 2008, the Canadian government announced the conclusion of its screening risk assessment stating: "*The current research tells us the general public need not be concerned. In general, most Canadians are exposed to very low levels of bisphenol A, therefore, it does not pose a health risk.***"**

  With respect to infants under 18 months, it said *"[s]cience 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."* Based on precaution, Health Canada is working with industry to achieve the lowest reasonably achievable levels of BPA in infant formula, and has recently finalized a regulation to ban polycarbonate baby bottles. The ban applies only to baby bottles and not to other polycarbonate bottles, tableware and food containers.

  In July 2009, Health Canada released several reports with new data on BPA in bottled water, baby food and infant formula. According to Health Canada, these new data confirm Health Canada's previous conclusion that "*the current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including infants and children.*"

Europe

- **European Food Safety Authority (EFSA)** – In January 2007, EFSA released a comprehensive scientific assessment of BPA that was conducted by a panel of independent scientific experts from throughout the European Union. The panel increased by a factor of five the safe intake level for BPA (known as the Tolerable Daily Intake or TDI) that was established in 2002, based on the panel's view that recent data provided more certainty about the safety of BPA.

  In July and October 2008, EFSA updated its 2007 assessment of BPA. EFSA reconfirmed its position that BPA-based polycarbonate and epoxy food contact products are safe for their intended uses. These updates examined recent data and concluded that newborns are able to metabolize. EFSA concluded that the TDI "*provides a sufficient margin of safety for the protection of the consumer, including fetuses and newborns.*"

- The **French Food Safety Authority** (AFSSA, February 2010), the **Danish Environmental Protection Agency** (October 2008), the **German Federal Institute for Risk Assessment** (BfR, January 2010), the **Dutch Food and Consumer Product Safety Agency** (VWA, November 2008), and the **Swiss Federal Office of Public Health** (BAG/OFSP, February 2009) have all re-evaluated BPA in light of recent studies and government decisions; all conclude that BPA is safe for use in food contact applications. Based on precaution, Denmark has implemented a temporary ban on food contact products for infants in Denmark; a recent Danish expert review found no clear evidence for harmful effects.

- **European Union** – In June 2008, an updated comprehensive **European Commission Risk Assessment Report** confirmed that BPA does not pose a risk to the general public from all current sources of exposure, including use of polycarbonate plastic and epoxy resins in consumer products. No bans or restrictions have been proposed. The update takes into account the latest scientific studies available (through 2007) and completes a comprehensive assessment undertaken on BPA over 10 years.

Japan

- **Japanese National Institute of Advanced Industrial Science and Technology** (affiliated with the Japanese Ministry of Economy, Trade and Industry) **–** In November 2005, a comprehensive report confirmed no risk of BPA to human health, including infants and children, and noted that no bans or restrictions are needed.

- **Japanese Ministry of Environment** – In 2005, based on its own comprehensive testing, concluded that there were no clear endocrine disrupting effects found at low doses and that no regulatory action is required to manage risks.

Australia and New Zealand

- **Food Standards Australia New Zealand (FSANZ** - an independent statutory agency responsible for setting food standards in the two countries) – In January 2010, FSANZ reaffirmed the safety of BPA and stated: *"FSANZ has assessed the studies that led to the USFDA decision to undertake a review and further research, and our view remains that BPA in baby bottles and food packaging in Australia and New Zealand is still safe."*

From: Jack Snyder
To: Williams, John (ECY);
cc: Matt Howe;
Subject: Comments on Children"s Safe Products - Reporting Rule
Date: Thursday, January 06, 2011 6:46:33 AM
Attachments: SIRC Child Safe Prod Rpt Rule Comments 1-6-11.pdf
ATT00001..c

Dear Dr. Williams,

Attached please find comments from the Styrene Information and Research Center (SIRC) on the Children's Safe Products - Reporting Rule, per the Rule Proposal Notice as revised in December. SIRC appreciates DoE's thoughtful consideration of these comments on the proposed inclusion of styrene in the Reporting Rule list.

Sincerely,

Jack Snyder

Jack Snyder
Executive Director
Styrene Information & Research Center
(703) 875-0729
jack_snyder@styrene.org

Styrene Information and Research Center (SIRC)
801 N. Quincy Street, Suite 700, Arlington, VA 22203-1730
Phone: 703-875-0736 Website: www.styrene.org

SENT ELECTRONICALLY

January 6, 2011

John R. Williams, Jr.
Washington State Department of Ecology
PO Box 47600
Olympia, WA 98540
john.williams@ecy.wa.gov

Re: Comments supporting the removal of the chemical styrene from the Children's Safe Products Reporting Rule

Dear Mr. Williams:

The Styrene Information and Research Center (SIRC)[1] appreciates the opportunity to provide comments on Rule Proposal Notice Chapter 173-334 WAC, Children's Safe Products - Reporting Rule.

SIRC supports the concerns voiced by other producers that the Department of Ecology (DoE) moved away from its position that the commonly accepted value for chemicals of concern in product components is 0.1% (1,000 ppm). The draft seems to require reporting trigger levels for each chemical at concentrations above 40 ppm. SIRC recommends that the rule clarify mandatory reporting only when intentionally added chemicals of concern are present at the levels above 0.1% (w/w) *de minimus* threshold.

SIRC believes that the DoE intended to focus the rules on those substances that are "intentionally added" to children's products, per their Phase 3 Report (http://www.ecy.wa.gov/programs/swfa/rules/pdf/p3text.pdf). Specifically the DoE states, "Ecology evaluated this recommendation and determined that for practical reasons, the focus should be on those chemicals that are intentionally added to children's products." Therefore, the Reporting Rule should be applied to the "intentionally-added" chemicals, i.e. added during the manufacture of the product or product component in the formulation or assembly of a

[1] The Styrene Information and Research Center's (SIRC's) mission is to evaluate existing data on potential health effects of styrene, and develop additional data where it is needed. SIRC has gained recognition as a reliable source of information on styrene and helping ensure that regulatory decisions are based on sound science. For more information, visit http://www.styrene.org.

consumer product to provide a specific characteristic, appearance, quality or to perform a specific function, which serves a purpose at or above 0.1% *de minimus* threshold.

In SIRC's view the scope of the above products ought to be limited to those regulated by the Consumer Product Safety Commission (CPSC) and should not include substances approved by the United States Food and Drug Administration (FDA).

SIRC believes that styrene monomer has been improperly included in the Draft List, does not meet the criteria required for the inclusion on the List, and respectfully requests the removal of styrene monomer from the reporting program under WAC 173-334 for the following reasons:

- **Styrene is a naturally occurring substance in the environment;**
- **Styrene is not intentionally added to children's products;**
- **Styrene is highly biodegradable and does not persist in the environment;**
- **Styrene is not known to cause cancer in humans;**
- **Styrene is not a reproductive or developmental toxicant, and does not cause disruption of the endocrine system;**
- **Styrene monomer exposures to children are very low.**

Styrene is a naturally occurring substance in the environment.

A Harvard Center for Risk Analysis study (Cohen *et al.*, 2002) reported that styrene is naturally present in food such as strawberries, beef, and spices, and is produced during the natural processing of food such as wine and cheese. The study reviewed all published data on the quantity of styrene contributing to the diet due to migration from food packaging and disposable food contact articles, and concluded there is no cause for concern for the general public from exposure to styrene migrating to food from styrene-containing materials in food-contact applications, such as polystyrene packaging and foodservice containers.

Styrene is not intentionally added to children's products.

Styrene monomer is a building block in the production of styrene-containing polymers such as polystyrene and acrylonitrile-butadiene-styrene (ABS). Most of the styrene monomer is polymerized, however the residual styrene monomer is available to diffuse out of the polymer into materials that are in contact with the latter. The FDA closely monitors the use of food additives or substances that might migrate to the food from packaging and serving materials and sets Acceptable Daily Intake (ADI) levels for these substances. The Agency has approved styrene for use as a food additive to enhance taste (i.e. chewing gum). FDA also approves the use of products in which there is a potential for the migration of styrene monomer. Estimated Total Dietary Intake (EDI) of styrene monomer from polystyrene food-contact polymers is 9μg per day (Lickly *et al.*, 1995). It is 10,000 times less than U.S.FDA's the acceptable daily intake (ADI) of styrene.
(http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=cediListing&id=1128)

A substantial body of literature has been developed to study the diffusion of styrene monomer from polymer packaging materials into food items in contact with the material. The diffusion model based on Fick's law of diffusion is also applicable for modeling the exposure of children mouthing plastics toys and other styrenic-based household objects that may be mouthed (Davies, 1974; Till *et al.*, 1982).

In 2002 Sciences International Inc. (Sciences) performed a screening-level risk assessment to determine the potential health impact of children's indoor exposure associated with styrene. This report addresses exposure associated with styrenic-based toys, other styrenic-based materials found indoors, in food, and in indoor air. This study was commissioned by SIRC. For the aggregate assessment using the U.S.EPA inhalation reference concentration, the typical total exposure for children less than 1 year of age was 2.0 µg/kg/day, and the hazard index was 0.0031 (320 times lower than the dose that would suggest any concern). For children less than one year of age, the upper-bound exposure was 6.9 µg/kg/day, and the hazard index was 0.011 (over 90 times below the dose that would suggest any concern). For older children, the exposures are even lower.

Styrene is highly biodegradable and does not persist in the environment.

A review of the published literature concludes that styrene is highly volatile in air. As a result of its biodegradability, transport of styrene through the air for appreciable distances (or its potential entry into water and soil) is unlikely in significant amounts from point-source emissions to the atmosphere (e.g. manufacturing facility emissions).

In a SIRC-sponsored study, Dr. Martin Alexander of Cornell University demonstrated that styrene has a half-life of three or four hours, and rapidly breaks down (i.e. within 12 hours) to carbon dioxide and water under aerobic conditions in soil or water. The potential for anaerobic biodegradation exists, but the few data available on anaerobic biodegradation suggest that the compound may persist in subsoils, anoxic aquifers, septic tanks, or sludge.

Measured environmental concentrations of styrene in the air, water and soil are too low to cause effects on mammals, non-mammals or microorganisms. Due to styrene's volatility and biodegradability its concentrations in the environment are well below established toxicity levels. Thus, bioaccumulation of styrene is unlikely to cause any harm.

In 1997, Dr. Alexander published an updated report entitled "Environmental Fate and Effects of Styrene" in the journal *Critical Reviews in Environmental Science and Technology* (Alexander, 1997).

Styrene is not known to cause cancer in humans.

The most recent collective cohort mortality studies—involving more than 55,000 workers in styrene-related industries in the United States and Europe over a 45-year period—show that styrene exposure does not cause cancer (or any other disease). The styrene levels to which some workers were exposed in the past were much higher than those encountered by today's workers. Since workplace exposures to styrene are as much as 10,000 fold higher than environmental levels, a lack of effect in workers is an indicator that general public exposure to current environmental levels of styrene should not cause adverse health effects. (IARC, 2002).

A comprehensive review of the potential health risks associated with exposure to styrene was conducted from 1999 to 2002 by a 12 member international expert panel selected by the Harvard Center for Risk Analysis (Cohen *et al.*, 2002). The scientists had expertise in toxicology, epidemiology, medicine, risk analysis, pharmacokinetics, and exposure assessment.

The conclusion was that was no cause for concern for the general public from exposure to styrene from food.

In 2009, a team of international experts in epidemiology reviewed studies of workers exposed to styrene in manufacturing and polymerization, in the reinforced plastics industry, and in styrene-butadiene rubber production (Boffetta *et al.*, 2009). They also reviewed studies of workers monitored for styrene exposure, studies of environmental exposure, community-based case-control studies of lymphoma and leukemia, and studies of DNA adducts. The conclusion if the panel was that the available epidemiologic evidence does not support a causal relationship between styrene exposure and any type of human cancer.

Styrene is not a reproductive or developmental toxicant, and does not cause disruption of the endocrine system.

The extensive database of toxicity studies that includes sub-chronic toxicity in three species, teratology studies in two species, two-generation reproduction with developmental neurotoxicity in rats, chronic/carcinogenicity studies in two species, as well as limited evaluations of reproduction and development in workers exposed to styrene has been reviewed by the NIEHS National Toxicology Program (NTP) Center for Evaluation of Risks to Human Reproduction (CERHR).

CERHR's styrene report is accessible at http://cerhr.niehs.nih.gov/evals/styrene/styrene.html.

The NTP reached its conclusion of "negligible concern for adverse developmental and reproductive effects resulting from styrene exposure in humans" stating "Studies in humans show no evidence that occupational exposures or exposures of the general population to styrene adversely affect reproduction or development. Further, data from experimental animal studies show no adverse effects at styrene doses far above human exposure levels."

Children's exposures to styrene monomer are very low.

In 2005, SIRC commissioned Exponent, Inc. (Exponent) of Alexandria, Va., to perform a "Probabilistic Risk Assessment for Exposure of Children to Styrene." The following pathways were considered: 1) ingestion of styrene from mouthing toys and other subjects, 2) ingestion of residue in food, 3) ingestion of residues in drinking water, 4) ingestion of residue in breast milk, and 5) ingestion of styrene in drinking water.

Exponent reviewed available literature on styrene monomer migration from plastic materials, children's mouthing behavior, styrene naturally occurring in food, and styrene measurements in indoor air. Additionally, an aggregate assessment combining all of these pathways was conducted to consider the total styrene ingestion exposure. By far, the lowest exposure estimates were for the mouthing pathway. Using a mass transfer model, the upper-bound exposure estimate for 3-18 month olds was only 0.0013 µg/kg/day. An aggregate assessment was also conducted to consider the combined exposures from all pathways. The highest aggregate hazard index across the age groups was for children 1-2 years of age where the hazard index was 0.0064, or more than 150-fold below the level of concern. The 50th percentile hazard index for children 1-2 years of age was 0.0027, which is 370-fold below the level of concern. It was concluded that chronic exposures to styrene are not a significant health concern for children.

SIRC commends DoE for including in its proposed regulations both a process for delisting an original CHCC substance (WAC 173-334-080), as well as intending "to revise the CHCC list on a regular basis" (WAC 173-334-060(2). Based on the assessment and study data cited above, SIRC believes that Ecology should remove styrene from the Reporting Rule list of substances given that it does not meet the criteria for listing. SIRC would welcome the opportunity to discuss this information in more detail, or provide additional information.

Very truly yours,

Jack Snyder, Executive Director
Styrene Information and Research Center
801 N. Quincy Street – Suite 700
Arlington, VA 22203
Jack_Snyder@styrene.org
(703) 875-0729

REFERENCES

Alexander, M., (1997) Environmental fate and effects of styrene, Crit Rev. Environ. Sci. Technol., 27, No. 4, 383-410.

Boffetta, P., Adami, H. O., Cole, P., Trichopoulos, D., Mandel, J.S. Epidemiologic Studies of Styrene and Cancer: A Review of the Literature (2009). Journal Of Occupational & Environmental Medicine, November 2009, volume 51, issue 11, pp.1275-1287. http://journals.lww.com/joem/Abstract/2009/11000/Epidemiologic_studies-of-Styrene-and-Cancer-A.5.aspx

Cohen, J.T., Carlson, G., Charnley, G., Coggon, D., Delzell, E., Graham, J.D., Greim, H., Krewski, D., Medinsky, M., Monson, R., Paustenbach, D., Petersen,B., Rappaport,S., Rhomberg, L., Ryan, P.B. and Thompson, K (2002) A comprehensive evaluation of the potential health risks associated with occupational and environmental exposure to styrene, J.Toxicol.Environ.Health,5 1-263.
(Summary report available at: http://www.hcra.harvard.edu/perspective.html)

Davies, J.T. (1974) Migration of styrene monomer from packaging material into food: experimental verification of a theoretical model. J.Fd. Technol., 9, 275-283.
IARC Monographs On The Evaluation Of Carcinogenic Risks To Humans, (2002) volume 82, IARC Press, Lyon, France.

Lickly, T.D., Breder, C.V.,& Rainey,M.L (1995) A model for estimating the daily dietary intake of a substance from food-contact articles: Styrene from polystyrene food-contact polymers. Regul. Toxicol. Pharmacol., 21, 406-417.

Probabilistic Risk Assessment for Exposure of Children to Styrene. Exponent Inc, 2005. (Report prepared for SIRC)

Screening-Level Exposure and Risk Assessment of the Potential Health Impacts to Children from Indoor Exposure to Styrene Monomer, Sciences International, Inc. October 21, 2002 (Report prepared for SIRC)

Till,D.E,Ehntholt,D.J.,Reid,R.C.,Schwartz,P.S.,Schwope,A.D.,Sidman,K.R., and Whelan, R.H. (1982) Migration of styrene monomer from crystal polystyrene to foods and foods simulating liquids. Ind. Eng. Chem. Fundam., 21,161-168.

From: Busch, Jon
To: Williams, John (ECY);
Subject: Comments on Children"s Safe Products Act from ACC Phenol Panel Jan 7 2011
Date: Friday, January 07, 2011 2:48:50 PM
Attachments: Scialli Analysis.PDF
2010-12-17 Final ACC Comments on Proposed WA CSPA Regs.pdf
RE CSPA--Basis of Phenol Listing (CAS # 108-95-2).msg
DARTIC 10-16-2003 Meeting.pdf
Final ACC Phenol Comments 01_07_11.pdf

To: Mr. John Williams, Washington State Department of Ecology (DOE):

The Phenol Panel of the American Chemistry Council (ACC) hereby submits its comments regarding the proposed Children's Safe Products Act. The comments specifically address issues relating to the "scorecard" for phenol, as well as issues relating to reproduction and developmental toxicity, which is an important theme related to this proposed regulation.

Please find attached several documents:

- The phenol-specific comments from the ACC Phenol Panel.
- A meeting transcript of the OEHHA/DART Identification Committee meeting held October 3, 2003, with the vote for phenol noted on pages 106-107.
- A letter dated October 9, 2003 from Dr. Anthony Scialli to members of the California DART Identification Committee. This letter includes results of an analysis of phenol studies relating to reproduction and developmental toxicity. I apologi e for the poor print uality, but it is the best copy I have.
- The comments submitted under separate cover by the American Chemistry Council, which were delivered to the DOE on December 17, 2010.
- An informal email exchange between you and me, where you identified specific references (studies) that the DOE and the Department of Health (DOH) may have used to evaluate phenol.

Over the years, the ACC Phenol Panel has sponsored both voluntary and mandated health effects testing for phenol. Because of their extensive involvement in health effects testing, I believe they are an excellent scientific resource, should the DOE/ DOH need further information. Please contact me if you have any uestions.

Could you please send a uick email to confirm that you received our submission.

Thank you for the opportunity to comment.

Kind Regards,

Jon

Jonathon T. Busch
Manager, Phenol Panel
Director, Chemical Products & Technology Division
on_busch americanchemistry.com
American Chemistry Council |700 – 2nd Street NE |Washington, DC| 20002
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Williams, John (ECY)

From: Williams, John (ECY)
Sent: Monday, November 15, 2010 10:53 AM
To: Busch, Jon
Subject: RE: CSPA--Basis of Phenol Listing (CAS # 108-95-2)

Hi Jon -

This is what I got back from our 'tox team' - please let me know if you require additional clarification.

With regard to the GHA rating of Phenol:

· The GHS source cited a study by Narotsky and Kavlock 1995 to classify phenol as toxic to reproduction (full citation is below). This study reported decreased live births in pregnant female rats when exposed orally to phenol during gestation days 6-19. The lowest observable effect was at 53 mg/kg/d and the no observable effect level was reported to be 40 mg/kg-d (described in ATSDR 2008).

· We tried to access the supporting study for the GHS rating of germ cell mutagenicity. It was cited as CERI-NITE Hazard Assessment No 32 (2005). WE located this assessment online but it was published in Japanese so we looked elsewhere for evidence of reproductive and development effects of phenol.

DOH used primarily the three references below to verify that supportive evidence existed for the GHS ratings.

OEHHA 2003 http://www.oehha.ca.gov/prop65/hazard_ident/pdf_zip/phenolDhid.pdf.

ATSDR 2008 http://www.atsdr.cdc.gov/ToxProfiles/tp.asp?id=148&tid=27;

REPROTEXT file for Phenol accessed 2010.

Evidence presented in these assessments show that in animals high levels of exposure (oral or inhal) during pregnancy resulted in dose-dependent fetotoxicity. Primary studies with supporting evidence were:

· Narotsky MG, Kavlock RJ. 1995. A multidisciplinary approach to toxicological screening: II. Developmental toxicity. J Toxicol Environ Health 45:145-171.

· NTP. 1983a. Teratologic evaluation of phenol (CAS No. 108-95-2) in CD-1 rats. National Toxicology Program. Research Triangle Park, NC: Research Triangle Institute.

· NTP. 1983b. Teratologic evaluation of phenol (CAS No. 108-95-2) in CD mice. Laboratory study: September 18, 1980 to January 12, 1981. National Toxicology Program. Research Triangle Park, NC: Research Triangle Institute.

· Ryan BM, Selby R, Gingell R, et al. 2001. Two-generation reproduction study and immunotoxicity screen in rats dosed with phenol via the drinking water. Int J Toxicol 20:121-142.

· York RG. 1997. Oral (gavage) developmental toxicity study of phenol in rats. Proctor & Gamble Company. Submitted to the U.S. Environmental Protection Agency under TSCA Section 8D. OTS0573686.

Human data is quite limited with respect to potential harm to children from phenolic compounds. A study of 2,075 infants exposed to phenolic disinfectants used to clean hospital nursery surfaces reported a significant increase in mean third-day microbilirubin level and an increase in the proportion of infants with a microbilirubin level >10 mg/dL (Doan et al. 1979). However, no cases of severe

jaundice were observed. Since infants did not come into direct contact with the cleaned surfaces, exposure was assumed to have occurred by inhalation of fumes (from ATSDR 2008).

-----Original Message-----
From: Busch, Jon [mailto:Jon_Busch@americanchemistry.com]
Sent: Thu 11/11/2010 2:19 PM
To: Williams, John (ECY)
Cc: Busch, Jon
Subject: RE: CSPA--Basis of Phenol Listing (CAS # 108-95-2)

Mr. Williams:

Thank you for sending the clarification in your email below. That was helpful. It was not just me that thought that Prop 65 was one at least one factor leading to listing, because one of the state's background documents says:

Chemical: Phenol CAS: 108-95-2 Toxicity

I. Developmental or Reproductive Toxicity

Worst

Severe

Bad

No

1. Prop 65

Identified as developmental or reproductive toxicant

Yes

I do know that phenol was never listed by Prop 65.

I would like to seek clarification on the remaining two factors driving the phenol classification of "Severe for developmental and reproductive toxicity". The two factors appear to be germ cell mutagenicity, and reproduction toxicity.

I have attached two documents, that I believe speaks to where Washington State is coming from. First, the Word document attached here is a summary of the basis for the state's listing. Second, when one uses the Japanese link you provided in your email below,

where more detailed information resides about phenol, and follow ultimately to the phenol data, one comes to the entry I have presented here as a pdf attachment. On page 154 of the pdf, for the germ cell mutagenicity entry, it is not clear why phenol is listed, and the entry begins by stating: "Based on the absence of data on germ cell multi-generation tests..". Is there a reference or set of references for this? I am particularly interested in the germ cell mutagenicity references: CERI-Nite Hazard Assessment No 32 (2005), and which NTP data base entry specifically? Then also for the reproduction entry, I believe it is the Narotsky and Kavaloc 1995 reference that led to listing, correct? I think I can obtain this article.

If you or your staff have any of the specific references that served as the basis for the phenol listing, I would like those. I would like to evaluate these in detail.

The Phenol Panel has sponsored and published a two-generation reproduction study on phenol for an EPA TSCA test rule, and another industry member has sponsored a developmental toxicity study on phenol (unpublished). Both of these were GLP guideline studies at the time. The Phenol Panel has sponsored and published genotoxicty work on phenol. The Panel also published a book chapter on phenol and phenolics (Patty's Industrial Hygiene). We have seen reviews by Canada, IARC, ATSDR, EPA/IRIS, OEHHA/Prop 65, etc. This is essentially from my recollection the first time we have ever seen phenol characterized as a repro toxicant, and certainly never a severe repro toxicant. The Prop 65 folks even reviewed phenol previously, and voted against listing because it did not meet their listing criteria. I have a key analysis developed by a Georgetown University professor that was instrumental in that decision. I do think the ACC Phenol Panel has some scientific resources and publications that may help Washington refine its CSPA analysis. More later.

Sorry, I did get the CAS #wrong initially..a typo on my part.

Kind Regards,

Jon

Jonathon T. Busch -Director, Chemical Products & Technology Division
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From: Williams, John (ECY) [mailto:jowi461@ECY.WA.GOV]
Sent: Wednesday, November 10, 2010 2:01 PM
To: Busch, Jon
Subject: RE: CSPA--Basis of Phenol Listing

Greetings -

Mr Busch -

This was checked and the listing is correct based on our methodology. Phenol (CAS# 108-95-2 - you cited #108-98-2, which doesn't seem to be associated with a chemical) is not listed by Prop 65, but that was not the basis for our classification. It was ranked "Severe" for Developmental or Reproductive Toxicity because of a Category 1B GHS classification for reproductive toxicity and germ cell mutagenicity (http://www.safe.nite.go.jp/english/ghs_index.html#results). It was also rated as A- in Reprotext.

Please let me know if you need additional clarification.

John Williams

-----Original Message-----
From: Busch, Jon [mailto:Jon_Busch@americanchemistry.com]
Sent: Wed 11/10/2010 7:33 AM
To: Williams, John (ECY)
Cc: Busch, Jon

Subject: CSPA--Basis of Phenol Listing

To: John R. Williams Jr., Department of Ecology
RE: Children's Safe Products Act (CSPA) regulations in Washington State:

I noticed in reviewing some background material regarding the CSPA that phenol (CAS # 108-98-2) was characterized as a high priority chemical of high concern for children was because it was listed by Washington state as having been identified as a developmental or reproductive toxicant under Prop 65. I have not seen phenol (CAS # 108- 98-2) ever listed under Prop 65 over the past 20 years, nor is it currently on the Prop 65 list based on my check of OEHHA's website as of yesterday, November 9, 2010 (list attached, which itself is dated Oct. 8, 2010). I do know that the DART Committee once reviewed phenol, and concluded it did not meet the criteria for listing as a developmental/reproductive toxicant. Having myself developed priority lists of chemicals for toxicological review, I do know that sometimes substances sneak onto such lists that should not be there. In the case of phenol, it can easily be confused with other phenol compounds because of the similar sounding name, but which have different CAS numbers. If the Prop 65 list is the primary basis for phenol being listed as a high priority, then perhaps phenol can be removed, or downgraded to a lower priority.

I will submit comments in the near future on this issue, but this is just a quick, initial read of what I see for now.

Kind Regards,

Jon

Jonathon T. Busch
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January 7, 2011

SENT VIA ELECTRONIC MAIL

Mr. John R. Williams
Washington State Department of Ecology
W2R HQ
P.O. Box 47775
Olympia, WA 98540-7775
jowi461@ecy.wa.gov

RE: American Chemistry Council Phenol Panel Comments on Proposed WAC 173-334

Dear Mr. Williams:

The Phenol Panel of the American Chemistry Council (ACC) appreciates the opportunity to comment on the Department of Ecologyôs (DOE) WAC 173-334, proposed regulations to implement the Childrenôs Safe Products Act.[1, 2] The safety of childrenôs products is of the utmost importance, and addressing the potential risks faced by children from possible exposure to chemicals is an important objective of the proposed regulations.

The ACC Phenol Panel also appreciates the extension of the comment period deadline from December 31, 2010 to January 7, 2011.

The ACC Phenol Panel fully supports the comments dated December 17, 2010 submitted separately by the American Chemistry Council (ACC). Moreover, the Panel urges the DOE to take additional steps to specifically correct errors in its score card for phenol, which serves as the basis for the listing of phenol (CAS # 108-95-2) as a chemical of high concern to children (CHCC). Two score card errors leading to phenolôs listing are noted below. The Panel believes that with the correction of these errors, phenol should subsequently be removed from the DOE list as a CHCC.

[1] ACC represents more than 140 leading companies engaged in the business of chemistry, including nearly 6,000 chemistry industry employees in Washington State. Our members apply the science of chemistry to make innovative products and services that make people's lives better, healthier, and safer. Our products are the foundation of virtually every industry, from medicines to fabrics, plastics to clean drinking water, cell phones to aircraft. ACC is committed to improved environmental, health, and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing.

[2] Members of the ACC Phenol Panel include companies that are major US producers of phenol. Panel members include: Dakota Gasification Company, Dow Chemical, Merisol USA LLC, Shell Chemical LP, and Sunoco Inc.

The DOE/DOH Score Card for Phenol Incorrectly Indicates that Phenol Has Been Identified Under Prop 65 as a Developmental or Reproductive Toxicant

The Department of Ecology/Department of Health (DOE/DOH) score card for phenol currently lists phenol as having been identified as a reproductive and developmental toxicant under Californiaôs Proposition 65. The basis of the score card information is reported to be a draft 2003 background document prepared by the staff of the California EPAôs Office of Environmental Health Hazard Assessment (OEHHA) (California EPA 2003). This draft OEHHA document, therefore, serves as one of the sources for placing phenol on the CHCC list. This draft background document was prepared by OEHHA for the stateôs expert Developmental and Reproductive Toxicant (DART) Identification Committee for consideration, which in turn evaluated in 2003 whether phenol should be listed as a reproductive and developmental toxicant under California Proposition 65. The references used by the DOE/DOH as the basis for listing phenol as a CHCC are all addressed in the OEHHA review (California EPA 2003, 2005), which includes: Doan et al. 1979, Narotsky and Kavlock 1995, RTI 1983a, RTI 1983b, Argus 1997, as well as the two-generation reproduction study sponsored by the ACC Phenol Panel (Ryan et al. 2001, ITT Research Institute 1999).

At its October 16, 2003, public meeting, the DART Identification Committee, which was convened by OEHHA, and which examined the references in the OEHHA review, concluded that phenol has NOT been ñclearly shown through scientifically valid testing according to generally accepted scientific principlesò to cause developmental toxicity, male reproductive toxicity, or female reproductive toxicity (California EPA 2005). The Committee so concluded in unanimously voting ñnoò to the following questions (Mank 2003):

- Has phenol clearly been shown through scientific valid testing, according to generally accepted principles, to cause developmental toxicity? Vote: 0-8, with one abstention (that is, none in support of a developmental toxicity finding: 8 opposed, and one abstention);

- Has phenol been clearly shown through scientific valid testing, according to generally accepted principles, to cause female reproductive toxicity? Vote: 0-9 (that is, none in support of a female reproductive toxicity finding: nine opposed, and no abstentions); and,

- Has phenol been clearly shown through scientific valid testing, according to generally accepted principles, to cause male reproductive toxicity? Vote: 0-9 (that is, none in support of a male reproductive toxicity finding: nine opposed, and no abstentions).

The record therefore indicates that phenol was NOT identified under California Proposition 65 as a reproductive or developmental toxicant, contrary to what the DOE/DOH score card suggests (see scorecard at page 183, phenol CAS # 108-95-2). This is a significant oversight by DOE/DOH leading to the listing of phenol as a CHCC; consequently, Washington Stateôs record for phenol needs to be corrected.

Importantly, the DOE/DOH failed to consider the vote and conclusion of the DART Identification Committee, the panel of experts on reproduction and developmental health

convened by OEHHA. The draft document prepared by OEHHA does not present the Committeeôs unanimous conclusions, nor does the draft document prepared by OEHHA staff necessarily reflect the Committeeôs expert scientific views. It is the ACC Phenol Panelôs view that DOE/DOH should consider the final judgment and conclusion reached by the DART Identification Committee, and that the DOE/DOH are obligated to cite the written, public conclusion of these experts in any future evaluations or score cards relating to phenol.

The final conclusion of the DART Identification Committee is noted in OEHHAôs final January 2005 report (California EPA 2005, at page 3), and the vote has been made public (Mank 2003, at pages 106-107). The current December 31, 2010 ñofficialò list of reproductive and developmental toxicants for California Prop 65 does NOT include phenol (California EPA 2010). To the ACC Phenol Panelôs knowledge, no new or major reproduction or developmental toxicity studies have been generated since the DART Identification Committeeôs review. Further, to the ACC Phenol Panelôs knowledge, no US or international regulatory agency to date has concluded that phenol is a reproductive or developmental toxicant (International Programme on Chemical Safety 1994, Health Canada 2000, US EPA/IRIS 2002, EU Risk Assessment 2006, ATSDR 2008). Gingell et al. (2001) also have reported in a published review of the phenol literature that ñPhenol does not appear to be a primary reproductive or developmental toxicant.ò

The DOE/DOH Score Card for Phenol Incorrectly Indicates that there is Developmental or Reproductive Toxicity Finding by the NTP CERHR

The score card for phenol currently indicates that there is a developmental and reproduction toxicity finding by the National Toxicology Programôs (NTPôs) Center for the Evaluation of Risks to Human Reproduction (CERHR). On March 20, 2000, the NTP CERHR announced that it was considering evaluating 11 chemicals, including phenol (Federal Register 2000). After reviewing public comments, the NTP CERHR deferred, and continues to defer, review of phenol due to evaluation of chemicals with higher priorities. As of January 7, 2011, the NTP CERHR website did NOT list phenol as one of the chemicals for which it has made an evaluation or finding (NTP CERHR 2011). Consequently, the NTPôs CERHR has NOT issued a finding to date for reproductive or developmental toxicity for phenol as the DOE/DOHôs score sheet suggests. This is another significant error by DOE/DOH, and this oversight leading to listing of phenol as a CHCC needs correction.

Analysis of Phenol Reproduction and Developmental Toxicity Studies by Dr. Anthony Scialli Indicates Phenol is not a Reproductive or Developmental Toxicant

At the time of California EPAôs Proposition 65 review of phenol in 2003, Dr. Anthony Scialli provided written comments to OEHHA and the DART Identification Committee on his analysis of the reproduction and developmental toxicity studies of phenol (Scialli 2003).[3] It is noteworthy that at the time of the Proposition 65 review, Dr. Scialli was serving as Principal Investigator for NTPôs CERHR.

[3]The ACC Phenol Panel retained consultant Dr. Jay Murray to assist with its own 2003 Prop 65 evaluation of phenol, and he in turn retained Dr. Anthony Scialli under a subcontract.

Below are selected excerpts from Dr. Scialliôs written comments, but the ACC Phenol Panel urges the DOE/DOH to review his full analysis in detail (Scialli 2003). Dr. Scialli writes as follows in his comments to OEHHA and the DART Identification Committee:

> My training…consisted of a fellowship with Sergio E. Fabro, M.D., Ph.D., one of the early investigators of thalidomide embryopathy and co-developer of the Brown-Fabro score, used in whole embryo culture evaluation. I am Professor of Obstetrics and Gynecology at Georgetown University Medical Center in Washington, D.C., Director of the Reproductive Toxicology Center in Bethesda, Maryland, and Founding Editor of Reproductive Toxicology, a leading peer-reviewed ournal in the field. I currently serve as Principal Investigator for the Center for the Evaluation of Risks to Human Reproductive, a pro ect of the National Toxicology Program. I am a member and Past President of the Teratology Society, and a member of the Organi ation of Teratology Information Services, the Society of Toxicology, the American College of Toxicology, and the European Teratology Society, among other professional and academic associations.
>
> My review of the literature included review of the draft Ha ard Identification Document dated July 2003 from the Office of Environmental Health Ha ard Assessment of the California Environmental Protection Agency and the published and unpublished reports cited therein. These reports involve research performed with experimental animals and reports from human populations in Poland, with translations of these latter reports into English.
>
> The reports from Poland show an association between histologic placental abnormalities and residence in a community that was contaminated by industrial activity. The use of urinary phenol concentration in these studies is taken as a proxy for exposure; however, the exposure cannot be concluded to have been solely to phenol. The presence of other chemical contamination in the community is likely, preventing the conclusion that phenol exposure is causally associated with the placental histologic abnormalities. There are no studies in humans showing that phenol causes reproductive or developmental toxicity.
>
> My approach to the experimental animal studies involved consideration of the role of general toxicity in producing adverse reproductive effects. Fetal growth, for example, relies on the transfer of calories and nutrients from the pregnant animal to the conceptus. If maternal feed intake is decreased due to inappetence or inanition, conceptus growth would be expected to be vulnerable. As another example, fertility in males and females relies on release of hypothalamic gonadotropin-releasing hormone (GnRH). GnRH release is inhibited by stress, mediated through opioidergic input from the periventricular region. If a chemical treatment produces generali ed toxicity, a conse uent decrease in GnRH and in reproductive function would not be unexpected. In these examples, the developmental and reproductive effects would be secondary phenomena, and not indicators of developmental or reproductive toxicity of the chemical under study.
>
> It has been common in risk assessment activities to compare general toxicity and target organ toxicity by comparing no observed adverse effect levels (NOAELs) or lowest observed adverse effect levels (LOAELs) for representative endpoints. The NOAEL/LOAEL approach relies on the doses selected in the design of the study and does not take into consideration the shape of the dose-response curve. A more complete comparison of the dose-response curves for general toxicity endpoints and for developmental/reproductive endpoints may be preferable. One approach that has been promoted by the US Environmental Protection Agency is the benchmark

> dose calculation. The benchmark dose is calculated from a model that uses the entire dose-response curve and represents the exposure level expected to produce a predetermined effect level, whether or not that dose was an administered dose in the study under evaluation.
>
> My evaluation of the phenol data base involved a comparison of benchmark doses for endpoints representing generali ed, development, and reproductive toxicity. The software available from the US EPA (http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm deid 20167) was used to calculate the dose associated with the upper bound of the 95 confidence interval around a 10 effect level (abbreviated BDML). Consistent with the recommendations of the model developers, I used data sets where pairwise statistical significance had been identified for at least one dose, or for which a significant trend had been demonstrated. Thus, I did not use the developmental data set generated by Kavlock, which showed no statistically significant alteration in litter si e, pup weight, perinatal loss, or litter biomass in spite of dose-related adverse effects on maternal weight gain, although this result is also consistent with my conclusion that phenol has not been clearly shown to cause reproductive or developmental toxicity.
>
> My general findings were consistent with the conclusion that developmental and reproductive effects associated with phenol treatment occur in the face of maternal or adult toxicity and are consistent with being secondary to that toxicity, rather than due to developmental or reproductive toxic effects of phenol itself.

Following a detailed and specific analysis of relevant phenol studies, Dr. Scialli concludes:

> In conclusion, an evaluation of dose-response curves in the phenol developmental and reproductive studies suggests that effects on development are secondary to impaired maternal health and are not due primarily to phenol exposure. Phenol has not been clearly shown to cause reproductive or developmental toxicity.

The ACC Phenol Panel urges the DOE/DOH to consider the scientific views and conclusions presented in Dr. Scialliôs analysis, which are consistent with the DART Identification Committeeôs conclusions, consistent with the conclusion of Gingell et al. (2001), and also consistent with the NTP CERHRôs relative low priority assigned to phenol over the years.

<u>The Phenol Panel Urges the DOE to Consider More Neutral Terms for Characterizing Developmental and Reproduction Toxicity</u>

The DOE/DOH currently uses the terms ñworst,ò ñsevere,ò and ñbadò as a means to prioritize and characterize phenol and other substances for developmental and reproduction toxicity on the individual chemical-specific score cards. These terms can be misleading, and can be misinterpreted by the public or regulatory agencies, which may use the DOE/DOH information for their own determinations and conclusions. Such terms also can unnecessarily frighten those in the public, who may not appreciate that these terms are meant for internal DOE prioritization purposes only. The ACC Phenol Panel instead proposes that the DOE/DOH adopt more neutral terms (or a more neutral description), so that the more neutral characterizations can be used for the legitimate purpose of prioritizing substances. Perhaps a priority characterization such as ñhigh,ò ñmedium,ò or ñlowò could be considered.

As a ñfinalò determination, the DOE/DOH score card for phenol currently designates phenol as a ñsevereò reproductive and developmental toxicant. Because phenol is not a developmental or reproduction toxicant, this characterization is both incorrect and misleading, and this characterization should be removed from the scorecard.

Actions for the DOE/DOH

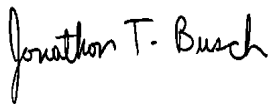
On the basis of (1) the vote and conclusions of the California Prop 65 DART Identification Committee, (2) the low priority assigned to phenol by the NTP CERHR over the years, (3) the conclusion by Gingell et al. (2001), (4) the past reviews by various US and international regulatory agencies that have not made a reproductive or developmental toxicity finding for phenol, and (5) the written analysis and clear conclusions Dr. Anthony Scialli, the ACC Phenol Panel supports the position that phenol is not a reproductive or developmental toxicant, as the DOE/DOH score card for phenol suggests. As a result, the Panel urges the DOE/DOH to:

- correct the score card record for phenol where errors exist, particularly as it relates to the correct Prop 65 conclusion and NTP CERHR information;
- remove phenol from the list of CHCCs;
- use more neutral terms to characterize reproduction and developmental toxicity when prioritizing phenol and other substances;
- remove the ñsevereò reproduction and developmental toxicity designation of DOE/DOH from the phenol score card; and
- consider the comments by the American Chemistry Council, dated December 17, 2010, which were submitted under separate cover.

* * * * *

The ACC Phenol Panel looks forward to working with you and DOE on this rulemaking. Because the ACC Phenol Panel has sponsored voluntary and mandated health effects testing on phenol over the years, it can serve as a scientific and information resource. If you have any questions, please contact me (jon_busch@americanchemistry.com; 202.249.6725). Thank you for considering our comments.

Sincerely,



Jonathon T. Busch
Director, Chemical Products & Technology Division
Manager, Phenol Panel

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CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

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SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

(PROPOSITION 65)

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MEETING OF THE SCIENCE ADVISORY BOARD'S

DEVELOPMENTAL AND REPRODUCTIVE TOXICANT (DART)

IDENTIFICATION COMMITTEE

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THURSDAY, OCTOBER 16, 2003

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ORIGINAL

HELD AT:

California Environmental Protection Agency
Headquarters Building
1001 I Street
Sacramento, California

Reported By: PHYLLIS MANK, CSR No. 5093

1 APPEARANCES

2 ---o0o---

3

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CALVIN HOBEL, Ph.D.
7 KENNETH JONES, M.D.
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8 HILLARY KLONOFF-COHEN, Ph.D.
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ED WEIL, ESQ.
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INDEX

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AGENDA ITEM		PAGE
I	Introduction	
	By Dr. Joan Denton	5
II	Consideration Of Chemicals As Known To The State To Cause Reproductive Toxicity	
	A. Propachlor	
	Staff presentation	
	By Dr. James Morgan	6
	Committee discussion	20
	Public Comments	N/A
	Committee discussion and decision	37
	B. Phenol	
	Staff presentation	
	By Dr. Marlissa Campbell	39
	Committee discussion	59
	Public Comments	
	By Dr. Jay Murray	77
	Committee discussion and decision	93

INDEX (Continued)

---o0o---

AGENDA ITEM		PAGE
III	Updates	
	Status of chemical listings via the administrative listing mechanisms	
	By Ms. Cynthia Oshita	108
	Status of the development of safe harbor levels	
	By Ms. Cynthia Oshita	109
	Status of hazard identification document preparation for perchlorate	
	By Ms. Cynthia Oshita	110
	Status of subcommittee discussions on prioritization procedure	
	By Dr. George Alexeeff	111
	Public Comment	N/A
IV	Summary of Committee Actions - Closing Remarks	
	By Dr. Joan Denton	112

1 SACRAMENTO, CALIFORNIA
2 THURSDAY, OCTOBER 16, 2003
3 ---o0o---
4 CHAIRPERSON MILLER: I think we're ready to
5 start our meeting for today.
6 We have two chemicals to consider, phenol and
7 propachlor, as well as some updates and other
8 administrative issues.
9 Before we start into our agenda, Joan Denton is
10 going to give a short introduction.
11 DR. DENTON: Thank you, Dr. Miller. I'm Joan
12 Denton, I'm the Director of OEHHA, and as is our norm, I
13 want to take the opportunity to introduce the committee
14 members the state's qualified experts who are sitting on
15 the Proposition 65 Developmental and Reproductive
16 Toxicant Identification Committee.
17 To my far right is Dr. Dorothy Burk, then Dr.
18 Calvin Hobel, then Dr. Ken Jones to my immediate right,
19 Dr. Miller, Dr. Carl Keen, Dr. Hillary Klonoff-Cohen,
20 Dr. Linda Roberts, Dr. Steve Samuels and finally Dr.
21 Patricia Shiono. Welcome to you all.
22 I would also like to take this opportunity --
23 some of you may not know that Colleen, who was our --
24 who was my -- the department's Chief Counsel, returned
25 to the Department of Toxic Substances Control in August,

1 so we do have a new Chief Counsel and that's Carol
2 Monahan. Carol, if you would stand.
3 Carol was Assistant General Counsel at Cal EPA,
4 and before that she worked at the Attorney General's
5 Office. Carol actually doesn't start until Monday, so
6 the -- our legal representation today will mainly come
7 from Ed Weil, who is a supervising Deputy Attorney
8 General with the Attorney General's Office, and who I am
9 sure is no stranger to anyone.
10 I think that's it. I'll turn it back to you,
11 Dr. Miller.
12 CHAIRPERSON MILLER: Moving to our first agenda
13 item, which is consideration of the chemical phenol, and
14 we'll start with the staff presentation from Jim
15 Morgan.
16 DR. MORGAN: Actually, we're changing the
17 agenda a bit on you. We're going to do propachlor
18 first.
19 CHAIRPERSON MILLER: Okay. I'm working from
20 what was on the website. So propachlor first.
21 DR. MORGAN: I'm Jim Morgan. I'm a
22 toxicologist with OEHHA. I want to briefly summarize
23 the developmental and reproductive toxicity with regard
24 to propachlor.
25 Propachlor is an acetanilide herbicide. It is

1 a solid at room temperature. It is used in agriculture
2 in the U.S. and other countries, but is not registered
3 or used in California. However, there is possible
4 exposure to people living in California from products
5 imported from other places.
6 Propachlor is rapidly absorbed and distributed,
7 metabolized and excreted with little tissue retention.
8 The metabolism is complex, with 11 metabolites having
9 been identified. It involves enterohepatic
10 recirculation, and the intestinal microflora. It is
11 mainly excreted in the urine.
12 Propachlor has been extensively studied for
13 pesticide registration purposes. RCHAS staff has
14 located no toxicity data in humans. In animals studies,
15 propachlor had relatively low acute toxicity by oral,
16 inhalation and dermal routes. However, it is a severe
17 eye irritant in rabbits.
18 In chronic and subchronic animal studies,
19 typical endpoints observed were reduced food
20 consumption, reduced body weight or weight gain, liver
21 hypertrophy, reduced kidney weight and occasionally
22 stomach lesions. Palatability was considered to be a
23 problem when administered in feed in high
24 concentrations.
25 Turning now to evidence on developmental

1 effects of propachlor, information is available from
2 rabbit and rat developmental toxicity studies as well as
3 rat reproductive toxicity studies.
4 Schardein, 1984, and Keller, 1987, reported a
5 rabbit developmental study. In this study, New Zealand
6 White rabbits were treated with propachlor by gavage at
7 up to 50 milligrams per kilogram per day. No adverse
8 maternal effects were attributable to propachlor
9 treatment, although each group had two or three maternal
10 deaths the cause of which was not determined.
11 Pre- and post-implantation losses were
12 increased at 15 and 50 milligram per kilogram per day,
13 although the effect was not statistically significant.
14 Litter sizes were reduced at 15 and 50 milligrams per
15 kilogram per day, which was statistically significant
16 only at 15 milligrams per kilogram per day.
17 Malformations, mainly skeletal, were increased
18 in all the propachlor-treated groups compared to
19 controls, and this was statistically significant at 15
20 milligrams per kilogram per day on a litter basis but
21 not on a fetal basis.
22 Subsequently, Adam, 1992, and Mercieca, 1992,
23 reported rabbit developmental studies which included a
24 rat range finding study and a main study.
25 In the range finding study, New Zealand White

1 rabbits were treated with propachlor by gavage at up to
2 225 milligrams per kilogram per day. Maternal deaths
3 occurred at 125, 175 and 225 milligrams per kilogram per
4 day, and all the animals died at the high dose.
5 Maternal weight loss during treatment was
6 observed at 125 and 175 milligrams per kilogram per day.
7 No developmental effects were observed, including pre-
8 and post-implantation losses, fetal weight or gross
9 external malformations.
10 In the main study, New Zealand White rabbits
11 were treated with propachlor by gavage at up to 116.7
12 milligrams per kilogram per day. Maternal deaths
13 occurred in the 116.7 milligram per kilogram group where
14 2 out of 20 animals died.
15 Maternal food consumption was reduced, and
16 weight loss during dosing was observed in the 116.7
17 milligram per kilogram per day group, which was a
18 statistically significant difference compared to
19 controls.
20 Early and late resorptions were higher, live
21 litter size was lower and fetal weight was lower in the
22 116.7 milligram per kilogram per day group, although
23 none of these effects were statistically significant.
24 There was no increase in malformations, but
25 there was an increase in a variation, bent hyoid arch,

1 in the 116.7 milligram per kilogram per day group, which
2 was statistically significant on a litter basis but not
3 on a fetal basis.
4 In the rat developmental studies, Mirkova,
5 1975, reported a study which was published in Bulgarian
6 and has been partially translated by OEHHA staff. This
7 study was poorly reported and difficult -- was difficult
8 to evaluate. In order to save time, I'm not going to
9 review that study here.
10 Suba, 1982, reported rat developmental studies
11 which included a range finding and a main study. In the
12 range finding studies, Sprague-Dawley rats were treated
13 with propachlor by gavage at -- up to 800 milligrams per
14 kilogram per day. All the females died at the three
15 highest doses.
16 Body weight and body weight gain during
17 treatment were lower in the 100 and 200 milligram per
18 kilogram per day groups. Pre-implantation losses were
19 higher and live litter sizes were lower in the 100 and
20 200 milligram per kilogram per day groups.
21 However, it should be noted that no indices of
22 variation or statistical tests were reported by the
23 author of this report.
24 In the main study, Sprague-Dawley rats were
25 treated with propachlor by gavage at up to 200

1 milligrams per kilogram per day. Maternal body weight
2 and weight gain were very slightly lower at 60 and 200
3 milligrams per kilogram per day, but the effect was not
4 statistically significant and no adverse developmental
5 effects were observed.
6 Specifically, pre- and post-implantation
7 losses, live litter size, fetal weight, frequencies of
8 malformations were all similar amongst groups.
9 Evidence on developmental toxicity is also
10 available from two rat reproductive toxicity studies.
11 Groya, 1986, reported a two generation study with one
12 litter in the first and two litters in the second
13 generation.
14 In this study, male and female Fischer 344 rats
15 were treated with propachlor in food at concentrations
16 adjusted to achieve doses up to 30 milligrams per
17 kilogram per day. No female deaths were attributable to
18 propachlor treatment.
19 In the F1 generation, food consumption was
20 reduced in the 30 milligram per kilogram per day group.
21 However, it was similar to controls in the F0
22 generation. There was no effect on maternal body
23 weights which was attributable to propachlor treatment.
24 No developmental effects were attributable to
25 propachlor treatment. Specifically, litter size, birth

1 weight and abnormalities were similar among groups for
2 all generations.
3 Lemen and Thake, 1995, reported a two
4 generation reproductive toxicity study with one litter
5 per generation.
6 In this study, Sprague-Dawley rats were treated
7 with propachlor in food at up to 2,500 ppm for males and
8 5,000 ppm for females. These concentrations
9 corresponded to doses of up to 400 milligrams per
10 kilogram per day for females and 166 milligrams per
11 kilogram per day for males. There were no deaths in the
12 F0 generation which were attributable to propachlor
13 treatment.
14 F0 female food consumption and body weights
15 were reduced at 1,000 and 5,000 ppm, and those were
16 statistically significant at some time points.
17 F0, F1 litter size and pup birth weight were
18 both reduced at 5,000 ppm and the effects were
19 statistically significant.
20 The F1 pup growth during lactation in this
21 study was severely reduced in the 5,000 ppm group and
22 pup survival after weaning was low. As a result, this
23 group was discontinued after weaning.
24 F1 female food consumption and body weights
25 were reduced at 1,000 ppm and the effects were

1 statistically significant. F1, F2 litter sizes were
2 similar among groups, and F1, F2 birth weights were
3 lower at 1,000 ppm, although the effect was not
4 statistically significant.
5 Turning now to evidence on female reproductive
6 toxicity, we have information available from two rat
7 reproductive toxicity studies as well as a number of
8 subchronic and chronic studies in rats, mice and dogs.
9 Groya, a 1986 study I described just previously,
10 there were possible indications of female reproductive
11 toxicity in that there was reduced fertility in the
12 F0/F1 mating at 3 milligrams per kilogram per day but
13 not at 30 milligrams per kilogram per day.
14 In the F1/F2a mating, there was reduced
15 fertility at both 3 and 30 milligrams per kilogram per
16 day, but in the F1/F2b mating, fertility was similar
17 among groups.
18 In the Lemen and Thake 1995 study, there was no
19 effect on fertility in the F0/F1 mating, and F0/F1
20 litter size and pup birth weight were both reduced in
21 the 5,000 ppm group, the effects of which were
22 statistically significant.
23 Again, for the second generation, the high dose
24 group was eliminated. Now, in the F1/F2 mating there
25 was no adverse effect on fertility, although the control

1 had unusually low fertility in this mating. F1/F2
2 litter sizes were similar among groups and the F1/F2
3 birth weights were lower at 1,000 ppm, which was not
4 statistically significant.
5 Female reproductive organ weights and pathology
6 have been examined in a number of studies, including the
7 two reproductive studies in rats, as well as subchronic
8 or chronic studies in rats, mice and dogs. No adverse
9 effects on ovarian or other female reproductive organ
10 weights or pathology were observed.
11 Turning now to evidence on male reproductive
12 effects of propachlor, information is available from the
13 two rat reproductive toxicity studies, a rat male
14 dominant lethal study and several chronic and subchronic
15 studies in rats, mice and dogs.
16 The Groya 1986 study, which I mentioned
17 previously, found reduced fertility in F0/F1 mating at 3
18 but not 30 milligrams per kilogram per day, in the
19 F1/F2a mating at 3 and 30 milligrams per kilogram per
20 day, but no differences in fertility in the F1/F2b
21 mating.
22 In the Lemen and Thake 1995 study, males -- the
23 male -- the high concentration in food corresponded to
24 average doses of up to 166 milligrams per kilogram per
25 day, and one mature male died in the F0 generation at

2,500 ppm and one died in the F1 generation at 1,000 ppm. The causes of deaths were not ascertained.

F0 male food consumption and body weights were reduced at 1,000 and 2,500 ppm. In the F0/F1 mating, fertility was similar among groups, but the litter size at birth was reduced at 2,500 ppm. In the F1/F2 mating, there were no effects on fertility, and F -- the litter sizes were similar among groups.

A male dominant lethal study was reported by Naylor in 1994. In this study, Sprague-Dawley rats -- male Sprague-Dawley rats were treated with propachlor in food at up to 2,500 ppm for ten weeks plus two rounds of mating.

These concentrations corresponded to average doses of up to 112 milligrams per kilogram per day. The females were not treated with propachlor. Food consumption and body weight were reduced at 1,000 and 2,500 ppm. The effects were statistically significant.

Fertility, implantations, resorptions and live litter size were similar among groups; that is, there were no dominant lethal effects observed.

Male testicular pathology was examined in a study by Zlateva and Maleva, 1979, which was published in Bulgarian and has been partially translated by OEHHA staff.

1 This study was poorly reported and it's
2 difficult to evaluate. And in the interest of
3 conserving time, I will not review it here, although it
4 is in the Hazard Identification Document.
5 Male testicular pathology has also been
6 examined in a number studies conducted with relatively
7 pure propachlor for pesticide registration purposes.
8 These include the reproductive studies in rats
9 and chronic and subchronic studies in rats, mice and
10 dogs. These studies consistently found no evidence of
11 testicular pathology which was attributable to
12 propachlor treatment.
13 Results for testes weights have been reported
14 in several studies, including studies in rats, mice and
15 dogs. Some of these studies found no effect of
16 propachlor treatment, while some studies found increased
17 testes weights and others found reduced testes weights.
18 Some of these differences were statistically
19 significant. However it, did not appear that there was
20 a pattern indicative of male reproductive toxicity in
21 these studies.
22 To summarize, in the developmental toxicity
23 studies, the study reported by Schardein, 1984, and
24 Keller, 1987, observed developmental toxicity,
25 specifically increased pre- and post-implantation

1 losses, reduced litter size and increased malformations
2 in the absence of maternal toxicity at relatively low
3 doses of 15 and 50 milligrams per kilogram per day.
4 The developmental study in rabbits reported in
5 Adam, 1992, and Mercieca, 1992, used the same strain of
6 rabbits, treated them for the same period of time as the
7 study reported in Schardein, 1984.
8 The developmental effects observed in the
9 Schardein study were not observed at similar doses 5.8
10 or 58 milligrams per kilogram per day in this study. At
11 a higher dose of 116.7 milligrams per kilogram per day
12 both maternal and developmental effects were observed.
13 Specifically, the maternal effects included
14 deaths for 2 out of 20 animals and substantial weight
15 loss during the dosing period. Developmental effects
16 included increased early and late resorptions, reduced
17 litter size and fetal weight, and increased bent hyoid
18 arch.
19 In the rat developmental studies reported by
20 Suba, 1992, no developmental effects were observed at
21 doses below the maternally lethal doses.
22 In the rat reproduction studies, the study
23 reported by Groya in 1986 observed no developmental
24 effects at relatively low propachlor concentrations in
25 food corresponding to doses of up to 30 milligrams per

1 kilogram per day.
2 In the rat reproduction study reported in Lemen
3 and Thake, 1995, they observed reduced live litter size
4 and birth weight in the presence of maternal toxicity at
5 the high concentration in food, which corresponded to a
6 dose of 400 milligrams per kilogram per day in the
7 females. Also observed severely reduced pup growth
8 during lactation at this same high concentration.
9 To summarize the female reproductive toxicity
10 data, in the rat reproduction study reported by Groya in
11 1986, there were inconsistent reductions in fertility at
12 relatively low concentrations of propachlor in food,
13 which corresponded to doses of 3 and 30 milligrams per
14 kilogram per day.
15 In the study reported in Lemen and Thake, 1995,
16 substantial effects on maternal food consumption and
17 body weight were observed at the high propachlor
18 concentration in food, which corresponded to a dose of
19 400 milligrams per kilogram per day.
20 No effects on fertility were observed at up to
21 this high dose. However, they did observe reduced
22 litter size at birth, birth weight and pup growth during
23 lactation at the high concentration of 400 milligrams
24 per kilogram per day.
25 Numerous studies in rats, mice and dogs

1 observed no effects on female reproductive organ
2 pathology or weight.
3 Turning now to summarizing male reproductive
4 toxicity, the rat reproduction study by Groya, 1986,
5 observed inconsistent reductions in fertility at
6 relatively low concentrations of propachlor in food,
7 corresponding to doses of 3 and 30 milligrams per
8 kilogram per day.
9 The rat reproduction study reported by Lemen
10 and Thake, 1995, observed male systemic toxicity,
11 specifically reduced body weight, at propachlor
12 concentrations in food corresponding to doses of 70 and
13 166 milligrams per kilogram per day.
14 They observed no effect on fertility at up to
15 the highest dose. They observed reduced litter size at
16 166 milligrams per kilogram per day.
17 The male dominant lethal study in rats which
18 was reported by Naylor in 1994 observed male systemic
19 toxicity in propachlor concentrations in food
20 corresponding to doses of 44 and 112 milligrams per
21 kilogram per day.
22 They observed no effect on fertility,
23 implantations, resorptions or live litter size; that is,
24 there were no dominant lethal effects observed.
25 Numerous studies conducted for pesticide

1 registration purposes examined testicular pathology and
2 weight. No effect on spermatogenesis or testes
3 pathology were observed by gross and/or microscopic
4 examination.
5 In regard to testes weight, some studies
6 observed no effect, while others observed increases or
7 decreases in weights. However, no pattern indicative of
8 male reproductive toxicity was apparent.
9 This concludes my presentation, and I'd be
10 happy to respond to questions at this time.
11 CHAIRPERSON MILLER: Any questions for Jim?
12 We'll then have a committee discussion followed
13 by an opportunity for public comment, and then
14 subsequently a committee decision.
15 So we have three reproductive endpoints to
16 really look at: developmental, male and female. I
17 think we should start, as we usually do, with
18 developmental toxicity for propachlor and open this to
19 the committee, and perhaps Linda Roberts, as our
20 developmental toxicologist, would be willing to open the
21 discussion.
22 DR. ROBERTS: Okay. Well, one of them.
23 CHAIRPERSON MILLER: Yes.
24 DR. ROBERTS: We have a number of cases where
25 studies have fairly high or fairly severe maternal

1 toxicity. Is this coming through okay? All right. If
2 you discount those situations, the amount of
3 developmental toxicity that's seen is very minimal.
4 For the rabbit studies, there is a slight
5 indication of skeletal effects, but it's not dose
6 responsive, it doesn't change any from 5 milligrams per
7 kilogram per day to 50. I am not convinced that it is a
8 clear indication of effect, and the rabbit studies were
9 really quite clean.
10 The reproduction studies do suggest that
11 there's a fair amount of postnatal development toxicity,
12 and those pups were very small, but it's my
13 understanding we don't consider postnatal effects in our
14 evaluation. And I don't think anything prenatal was
15 strong enough to convince me that it's clearly indicated
16 as causing developmental toxicity.
17 DR. JONES: So, Linda, is there anything that's
18 significant about a bent hyoid arch?
19 DR. ROBERTS: It's not an uncommon finding. I
20 know its ossification is quite variable. In fact, once
21 I started off with a real job, one of the first
22 situations I came across was a change in hyoid
23 ossification, and I actually called a teratologist at
24 the State of California for advice on ossification
25 endpoints, and her comment to me was, "It wasn't the

1 hyoid, was it?"
2 I'm not really sure what a bent hyoid
3 indicates, and I'm not certain that it's going to be
4 consistent from one laboratory to another.
5 Carl, your -- do you have any comment on that?
6 DR. KEEN: No, I agree. I mean, we've seen it
7 occasionally, and we put it as more in the anomaly
8 category than abnormality, which I think is a fairly
9 important distinction.
10 DR. DONALD: Just to expand on something that
11 Dr. Roberts said, with regard to postnatal effects,
12 effects that are manifest postnatally but which could be
13 the result of prenatal exposures are definitely covered
14 by the statute.
15 There's also the issue of whether lactational
16 exposures, where the chemical is being -- or where the
17 exposure is postnatal, but it's the result of
18 contamination of the maternal milk could be considered a
19 female reproductive effect, so you do have some latitude
20 in that area.
21 CHAIRPERSON MILLER: I did look in the
22 literature for the half-life of propachlor in some
23 animal and models, and I actually couldn't find it in
24 terms of blood half-life versus urinary excretion and
25 total amounts in the urine and -- I assume it's very

1 rapid.
2 Was the State able to find that information?
3 DR. MORGAN: I'm not sure. I don't actually
4 remember. It's there -- there is one page in the HID on
5 it under the pharmacokinetics where, basically, we just
6 took the information summarized by US EPA, and we didn't
7 really look any farther on it.
8 CHAIRPERSON MILLER: Because that would be a
9 real consideration in terms of milk amounts; and that if
10 it's very rapidly metabolized, that could explain the
11 very low values that they actually measured in some --
12 in milk in the goat study.
13 DR. MORGAN: Yeah, it is clear that it is
14 metabolized very rapidly and excreted very rapidly.
15 It's on the order of hours to get rid of it.
16 CHAIRPERSON MILLER: But it then -- it also
17 seems to move around the body quite well; and,
18 therefore, if there's high blood levels, you could have
19 moments of high milk levels associated with that.
20 DR. SHIONO: I have a question, Linda, about
21 the studies that do show significant increase in
22 malformations, and I'm wondering how -- in the rabbits,
23 I'm wondering how you interpret those?
24 DR. ROBERTS: Okay, let me get my two rabbit
25 pages out of here.

1 In looking at the Schardein study -- first of
2 all, control rabbits, if you have a study from the -- a
3 group size of between 12 and 20 -- previous guidelines
4 required 12 pregnancies per group, current guidelines
5 for rabbits require 20, I believe -- you would expect to
6 see somewhere between no malformations within the entire
7 litters or a handful, and they tend to be of various
8 types of endpoints, but ossification both in rats and
9 rabbits tends to be the place where you're most likely
10 to see malformations or anomalies.
11 If the 3 out of 63 or 7 out of 58 were real
12 findings, which are the -- and those are the
13 malformation incidences or findings for the 5 and 15
14 milligram per kilogram per day groups in the Schardein
15 study, then I would expect that we'd see more than 3
16 out of 82 at 50.
17 To be honest, there is no real difference to me
18 between 0 out of 96 and 3 out of 63, and 3 out of 82
19 even has a lower incidence. So we have only the 15
20 milligram per kilogram per day group that suggests that
21 malformations occur.
22 There were no findings of malformations in the
23 range finding study, Adam, '92, but above 75 milligrams
24 per kilogram per day I think there were only one or two
25 litters. And not finding anything in just one or two

1 litters, I think, doesn't tell us anything positive or
2 negative about it.
3 The incidence of malformations in the Adam,
4 '92, study really doesn't change for external and
5 visceral. It -- there's a suggestion that there is
6 skeletal; but, again, once you get up to the 116, and
7 you still have a pretty decent size group, you're back
8 up to no malformations at all. And that's part of -- or
9 a large part of why I am not convinced that it's outside
10 of the range of rabbit variation.
11 DR. SHIONO: So it could just be a statistical
12 sampling error that this one mid range dose group had an
13 increase in malformations?
14 DR. ROBERTS: Yeah, in skeletal malformations,
15 the 3 out of 116 in the control does not, to me, look
16 particularly different from 5 out of 122.
17 CHAIRPERSON MILLER: We didn't discuss the
18 Bulgarian study at all in the OEHHA review. Is there
19 any -- do we need to comment on it or --
20 DR. ROBERTS: I'd like to make one comment that
21 the end life conduct from what was described in the
22 Hazard Identification Document, you know, it's --
23 there's not a lot there, but it seemed to be a
24 scientifically approachable approach, and they're the
25 only developmental study that had gestational exposure

1 from gestation day one all the way up to gestation day
2 20.
3 When there's only 65 percent of the test
4 material known to be propachlor and no information about
5 the other 35 percent, I think Dr. Morgan took the
6 correct approach about minimizing its influence on the
7 rest of the Hazard Identification Document.
8 CHAIRPERSON MILLER: Any further comments from
9 the committee or discussion by the committee?
10 DR. HOBEL: Yes, I have a -- I was very
11 interested in the effect of -- of the use of this
12 chemical on nutrition and the changes in maternal weight
13 and also its effect on fetal weight.
14 And I make this comment because I think this
15 plays a very important role in the developmental things
16 that we're interested in and, at the same time, it tends
17 to program the fetus for what happens during the
18 neonatal period.
19 This issue about lactation, it may not be the
20 drug in -- in the milk, but it may be the lack of
21 adequate substrate in terms of its nutritional
22 value and -- and may have nothing to do with the drug at
23 all.
24 So -- and that really hasn't been addressed in
25 any of these studies in terms of the content of the milk

1 and the amount of potential calories that the pup could
2 get from -- from nutrition. So I think nutrition plays
3 a very important role in what effects are being observed
4 in most of these studies as a single factor.
5 And I don't think any of the studies have
6 really taken into account the effect of these various
7 insults, whether it's a drug or nutrition or behavior
8 that ultimately has effect on development. That makes
9 it very complex.
10 So I think the nutritional effect of --
11 especially in the very high doses, is -- is very
12 interesting and tells me that, in doing studies like
13 this, whether you give it orally or in the food may be
14 very important. End of comment.
15 CHAIRPERSON MILLER: It's a good comment, but
16 the studies would have to be designed very differently
17 to address it.
18 DR. KEEN: Maybe I'll just slightly tag onto
19 that, though. I mean, I certainly agree, but one of the
20 principles, I think, that we work under is that if the
21 agent that's being studied results in maternal
22 reductions in food intake, that really is a sign of
23 maternal toxicity.
24 And then, in the absence of having restrict fed
25 groups to pair up with it, that usually does not provide

1 evidence for direct effects of the agents on embryonic
2 or fetal development.
3 In terms of your comment on milk composition,
4 it certainly is possible. It's fairly unusual to have
5 an agent that alters milk composition, per se. It's not
6 unusual to have agents which can potentially result in
7 changes in milk yield.
8 But those are very, very difficult to actually
9 conduct the appropriate controls there. And, again,
10 typically they'd be viewed as signs of maternal
11 toxicity, which would then -- is something we'd need to
12 take into consideration.
13 DR. HOBEL: Yeah. I was thinking more about --
14 there are several things. It could affect the release
15 of oxytocin in terms of let down of milk from the
16 breast, so it could affect the delivery system at the
17 time of suckling.
18 CHAIRPERSON MILLER: Are we -- any other
19 comments on developmental, or are we --
20 DR. SAMUELS: I'll just say that, in looking at
21 the Schardein and Keller study, though apparently the
22 results weren't statistically significant, I saw -- a
23 number of the implantation/post-implantation litter
24 size, implantation pre and post loss, showed at least
25 apparent trends which don't seem to have been reported

1 as tests -- by tests.
2 However, those trends did not appear in the
3 other rabbit study and in the -- which was the Adam and
4 Mercieca study. And in the mice studies, it apparent --
5 the chemical appeared to be good for fertility.
6 So while I think there may have been something
7 going on in the individual -- I'm thinking of Suba study
8 and the rat study -- sorry -- so while I thought there
9 may have been something going on at least in the
10 Schardein study, I can't see that it's replicated in the
11 others or -- and so I didn't -- don't take that as
12 evidence of toxicity.
13 CHAIRPERSON MILLER: Those are all very useful
14 comments. So if there's no more in developmental
15 toxicity, perhaps we can address any issues about female
16 reproductive toxicity.
17 DR. BURK: I have a few comments there.
18 The relevant studies are the two rat
19 reproduction -- reproductive toxicity studies and then
20 the numerous chronic and subchronic studies where they
21 looked at organ weights and/or pathology, and all of
22 those were negative. So nothing with the ovaries
23 weightwise or pathologically speaking.
24 When we look at the two generation studies,
25 again, the Groya, '86, there were some cases of reduced

1 fertility, but there wasn't -- it was, as said in the
2 document, sort of sporadic. There wasn't anything
3 consistent about it in terms of dose response or even
4 between the two litters, so it's hard to make anything
5 of that.
6 The other study, Lemen and Thake, much higher
7 doses, concentrations and more systemic toxicity.
8 Again, no adverse effects on fertility, a number of
9 endpoints.
10 The main thing I wanted to bring up, though,
11 that already we started to discuss, was the issue of the
12 adverse effects on the pups during lactation which
13 seemed to be pretty clear. I mean, at birth, you know,
14 they were somewhat less in weight, but by the weaning
15 time they were significantly lower in weight than the
16 controls.
17 So, again, I don't know if we can turn that
18 into clear female reductive -- reproductive toxicity,
19 but it is an interesting thing to discuss. It appears
20 to be an effect of lactation rather than what Linda was
21 mentioning as a prenatal effect that carries over into
22 postnatal time.
23 But without more detail, as we've heard here,
24 we don't know if it's, you know, a direct effect of the
25 propachlor, a nursing effect, a yield effect, a

1 nutritional effect, impaired lactation, what have you,
2 but I think it is -- it is a real effect. Again, it's
3 at maternally toxic levels.
4 Does anyone have any other comments on the
5 lactation or have we discussed that enough? I guess my
6 question is: Would we consider it a female reproductive
7 toxicant effect?
8 CHAIRPERSON MILLER: I think without some data
9 it's difficult. I'd really like to know what the actual
10 blood levels were, you know, over a time period rather
11 than one window of time measurement.
12 DR. BURK: You mean, to know if -- if it's the
13 propachlor --
14 CHAIRPERSON MILLER: Yes.
15 DR. BURK: -- itself or --
16 CHAIRPERSON MILLER: Yes.
17 DR. BURK: Exactly.
18 CHAIRPERSON MILLER: And then you could also
19 design different experiments, but we don't have those.
20 DR. KEEN: I mean, in response to your
21 question, typically one doesn't look at lactation
22 capacity or ability as an indicator of maternal
23 toxicity. That would be a -- slightly different.
24 I find -- in the absence of, say, a
25 cross-fostering study, very, very difficult to sort out

1 a -- there is an effect here in a study; but as you
2 said, again, it's with frank maternal toxicity.
3 A common sign of maternal toxicity is
4 everything from litter abandonment to, you know, refusal
5 to go ahead and allow suckling, but those are not really
6 reproductive toxic effects, you know, by most
7 individuals' definition.
8 So without -- in my opinion, one would almost
9 have to have the cross-fostering to answer the question
10 and coupled with, you know, no composition data -- both
11 which would be very nice pieces of information -- but in
12 the absence of them, I don't see anything which is clear
13 or unequivocal in the current studies.
14 DR. SAMUELS: I'm looking at Tables 17 and 18
15 from the Lemen and -- how do you say their names --
16 Lemen and Thake study, 1995, and I notice that on
17 postnatal day 0, the pup weights are already reduced in
18 the higher dose groups.
19 And, of course, that -- and -- but there's
20 still a dose response in that the 100 milligram -- 100
21 part per million per day group is reduced relative to
22 the control, and that's true in both the F1 and the F2
23 pups.
24 So it's not clear when those weights were
25 taken, but that does seem to me to be an early sign of

1 effect on the pups that would be due less to lactation
2 than the weights on the other postnatal days.
3 They're not called birth weights because
4 apparently they weren't measured at birth, and so there
5 apparently was some lactation.
6 DR. BURK: Yeah, that's -- that's true.
7 CHAIRPERSON MILLER: Any more comments on
8 female reproductive toxicity?
9 DR. KEEN: Again, maybe just a quick so we
10 don't leave that, I think, floating there. There was
11 approximately a 50 percent lower food intake in that
12 5,000 group towards the end of gestation. So the fact
13 that you're going to see lower pup weights is -- if you
14 didn't see it, I would be very concerned.
15 DR. SAMUELS: I'm discounting the 5,000 group.
16 That's, obviously --
17 DR. KEEN: Okay.
18 DR. SAMUELS: -- too high.
19 DR. KEEN: Okay.
20 DR. SAMUELS: But you see the trend in the
21 other three groups as well.
22 DR. KEEN: Right. I guess I'm always wary of
23 trends. I'm going with statistical significance, and
24 they're not statistically significant so -- I mean,
25 again, I'm using the clear and unequivocal sort of

1 inspection of the data.
2 DR. SHIONO: But they are -- the highest dose
3 group does have a statistically significant decrease,
4 right?
5 DR. KEEN: Yes. That's the 5,000 group, and
6 maternal food intake was one-half of what it was in the
7 other groups. So the fact that you're going to -- you
8 know, if you express pup weight as a function of
9 maternal body weights, you would say, wow, these are
10 monsters, they're great and large. I mean, it just is
11 not the appropriate way.
12 If you were a restrict fed group here, you
13 would see certainly this level of reduction in birth
14 weight or postnatal day one weight, so it's very
15 predictable.
16 And it's clearly, in this particular case,
17 associated -- at least one could argue strongly it would
18 be associated with signs of maternal toxicity when you
19 see food intakes one-half, and that's over a period of
20 several days, which would suggest that towards delivery
21 it could even be more of a pronounced reduction.
22 DR. ROBERTS: One note about the first
23 generation in the Lemen and Thake study. At the 5,000
24 ppm where we have the severe toxicity, we have not only
25 a smaller live litter size at birth, but quite a bit

1 smaller pup weight.
2 If we look at the other three groups, the 0,
3 the 100 and the 1,000 part per million, we actually have
4 a trend towards an increase in live litter size at birth
5 and a slight trend towards -- in both cases it's a
6 slight trend -- and then also a slight trend towards the
7 birth weight being down. I'll call it birth weight.
8 It's the closest they can get to birth weight really.
9 From that standpoint, I'm not sure if the live
10 litter size being slightly larger accounts for some or
11 all of the postnatal day 0 pup weight being slightly
12 smaller. That was not true, though, in the F2
13 generation.
14 CHAIRPERSON MILLER: We seem to be relying on
15 two fertility studies quite heavily for all three
16 reproductive endpoints. So is there any additional
17 discussion in terms of female reproductive toxicity?
18 Okay, we'll move on to discuss male
19 reproductive toxicity. Again, looking at the Groya and
20 the Lemen and Thake studies -- and it looks like I'm the
21 male reproductive toxicologist, so I'll probably make
22 some comments about that -- I will make comments about
23 that.
24 In agreement with Dr. Burk, in looking at the
25 same studies that really have a fertility endpoint, you

1 can't distinguish, based on fertility, between male
2 and -- male or female effects.
3 So we're looking at the same endpoints and
4 we're drawing the same conclusions, which was, with
5 those fertility studies which don't necessarily
6 distinguish between a male effect versus a female
7 effect, we saw no consistent dose response
8 relationships, as indicated in Dr. Morgan's
9 presentation. So the fertility changes were not totally
10 consistent with a dose response relationship.
11 And as for the females, the male histopathology
12 was indicative of no effects, and numerous studies in
13 rats, mice, dogs showed no evidence of male reproductive
14 histologic damage.
15 Other than the study from Bulgaria, which as
16 Linda -- as Dr. Roberts indicated was rather limited in
17 its interpretation due to the fact that the test
18 substance was only 65 percent of the compound that we're
19 currently discussing, there was no evidence for a
20 dominant lethal effect in terms of male reproductive
21 damage.
22 Consistently -- as with all studies, there was
23 consistent losses in body weight and reduction in food
24 consumption at the high dose levels associated with a
25 generalized systemic toxicity in both males and

1 females.
2 Testes weight changes were noted. These were
3 not always consistent. They were increased, decreased
4 or the same in various studies.
5 I did a little calculation in my head, thinking
6 of, okay, is there decreased body weight compared to
7 decreased testes weight, and, you know, that kind of
8 worked out.
9 If it's ten percent less, you got ten percent
10 decrease in testes size, but then some animals you see a
11 decrease in body weight and no change in testes size.
12 So, again, this lack of consistency concerned
13 me between studies, and the changes were not always of
14 large magnitude. And so I didn't find any compelling
15 evidence for male reproductive toxicity.
16 I open up to discussion with the committee.
17 Are we ready to -- we're open for public
18 comment, the next step, and I have no little blue cards
19 up here, so I don't see any interest in public comment,
20 which means, are we ready as a committee to move on to a
21 decision or any further comment?
22 There's been some minor changes in the voting
23 procedure. In the past we've voted on whether something
24 causes a particular type of toxicity and does it cause
25 or then does it not cause.

1 This seems a little unwieldy in our approach to
2 voting, so we're very simply going to vote: Does
3 chemical X by the usual statute and wordage cause X, Y
4 or Z reproductive toxicity? And then I will ask for a
5 vote for all those voting yes, all those voting no, all
6 those abstaining, for each endpoint of toxicity. So
7 this, I hope, will make it a little clearer exactly what
8 we're voting on.
9 So for propachlor the question is: Has
10 propachlor been clearly shown through scientifically
11 valid testing, according to generally-accepted
12 principles, to cause developmental toxicity?
13 All those voting yes, please raise your hand.
14 All those voting no, please raise your hand.
15 I think this is unanimous, so I don't need to
16 ask for all those abstaining to raise their hands.
17 So for the next toxicological endpoint: Has
18 propachlor been clearly shown through scientifically
19 valid testing, according to generally-accepted
20 principles, to cause female reproductive toxicity?
21 All those voting yes, please raise your hand.
22 All those voting no, please raise your hand.
23 Again, a unanimous decision with all nine
24 committee members voting no. Therefore, we don't need
25 to ask -- request abstaining information.

1 Male reproductive toxicity: Has propachlor
2 been clearly shown through scientifically valid testing,
3 according to generally-accepted principles, to cause
4 male reproductive toxicity?
5 All those voting yes, please raise your hand.
6 All those voting no, please raise your hand.
7 A unanimous number again with nine voting no.
8 So I think we can move on -- I anticipate a
9 break around 11:30, but I think that gives us at least
10 sufficient time for the staff presentation associated
11 with our second chemical of phenol, and that's going to
12 be -- the presentation is going to be made by Dr.
13 Marlissa Campbell.
14 DR. CAMPBELL: Good morning.
15 This presentation will be a brief overview of
16 the information presented in the Hazard Identification
17 Document, evidence on the developmental and reproductive
18 toxicity of phenol.
19 Phenol is a monohydroxy derivative of benzene,
20 which is sometimes known as carbolic acid. It is a
21 high-volume production chemical used in the housing,
22 construction and automotive industries as well as in
23 consumer products such as throat lozenges.
24 Exposure may occur in the workplace via
25 contaminated air, water or foodstuffs, or through the

1 use of phenol-containing consumer products.
2 Phenol is readily and rapidly absorbed by all
3 roots of exposure. It distributes rapidly throughout
4 the body, including the embryos and placenta of
5 experimental animals.
6 Metabolism is primarily by Phase II conjugation
7 reactions and secondarily by Phase I oxidative reactions
8 to dihydroxy products. Unchanged phenol can also be
9 excreted in the urine.
10 Clearance of phenol from the body is rapid with
11 elimination primarily through urinary excretion.
12 Results from controlled dermal and inhalation exposures
13 have indicated a half-life in the human body of
14 approximately three-and-a-half hours.
15 Human deaths have occurred following ingestion
16 of phenol as well as by dermal exposures involving large
17 areas of skin. The minimum reported lethal oral dose in
18 humans was 4.8 grams or approximately 70 milligrams per
19 kilogram. Death occurred within ten minutes.
20 Symptoms of acute toxicity in humans and
21 animals include extreme irritation of skin and mucous
22 membranes, muscle weakness, tremors, loss of
23 coordination, paralysis, convulsions, coma and death.
24 Central or peripheral nervous system toxicity is
25 presumed to be the primary cause of death.

1 Chronic and subchronic exposures of
2 experimental animals to phenol by the oral route have
3 been associated with reductions in feed and water
4 consumption, accompanied by reduced body weight gain.
5 US EPA has classified phenol in Group D, or not
6 classifiable as to human carcinogenicity. Phenol has
7 been shown to have promoting activity when applied
8 repeatedly to mouse skin.
9 In a study reported only in abstract form,
10 Hernberg reported on data from the Finnish Register for
11 Congenital Malformations. Interviews of 1,047 registry
12 mothers were compared to an equal number of referents.
13 Overall, this study did not indicate meaningful
14 associations between maternal exposure to disinfectants
15 and the occurrence of congenital defects.
16 In another study, Axelsonn studied pregnancy
17 outcomes among 576 pregnant lab workers exposed to
18 organic solvents to the outcome for an equal number of
19 unexposed pregnancies.
20 The relative risk for miscarriage was 1.31 with
21 a 95 percent confidence interval of 0.89 to 1.91.
22 Perinatal death rates and malformation frequency did not
23 differ between the groups. While many of these workers
24 may have been exposed to phenol in combination with
25 other solvents, for those five individuals who

1 specifically reported phenol exposures, pregnancy
2 outcome was normal.
3 Research Triangle Institute completed pilot and
4 full-scale standard developmental toxicity studies by
5 the gavage route of exposure in both rats and mice.
6 In the rat pilot study, both fetal and maternal
7 weights show trends for decreasing with increasing dose
8 of phenol. The full-scale rat study gave no evidence
9 for maternal toxicity. Fetal weights were significantly
10 decreased at 120 milligrams per kilogram with a
11 significant trend over all doses. There were increased
12 numbers of litters with resorptions at doses of 30 and
13 60 milligrams per kilogram, but not at the highest dose
14 of 120 milligrams per kilogram.
15 In the mouse pilot study, malformations,
16 decreased fetal body weights and effects on viability
17 were seen at doses associated with reduced maternal
18 weight gain during treatment.
19 In the full-scale mouse study, fetal body
20 weights were decreased at the high dose of 280
21 milligrams per kilogram with a significant trend over
22 all doses.
23 Dams showed increased mortality, as well as
24 decreased body weights and weight gain at 280 milligrams
25 per kilogram. Tremors and other clinical signs were

1 seen at 140 and 280 milligrams per kilogram.
2 Argus Laboratories conducted pilot and
3 full-scale developmental toxicity studies in the rat by
4 the gavage route of exposure. No significant effects
5 were reported in the pilot study.
6 In the full-scale study, decreased fetal body
7 weights were seen at the high dose of 360 milligrams per
8 kilogram, one incident of a rare malformation was seen
9 at 360 milligrams per kilogram, another at the mid dose
10 of 120 milligrams per kilogram.
11 Dams showed reduced body weight and gestational
12 weight gain at 360 milligrams per kilogram as well as
13 clinical symptoms and one death. Reductions in body
14 weight gain during treatment were seen at 360 and 120
15 milligrams per kilogram.
16 Kavlock gave rats a single dose of phenol by
17 gavage on gestation day 11. Live-born offspring from
18 the 667 and 1,000 milligram per kilogram group showed
19 kinked tails and limb paralysis. Maternal animals
20 showed altered respiration and reduced weight gain.
21 Narotsky and Kavlock, in another study, gave
22 rats 0, 40 or 53.3 milligrams per kilogram phenol by
23 gavage on gestation days 6 through 19.
24 In both treated groups, the numbers of live
25 pups per litter were reduced on postnatal days 1 and 6.

1 Two pups in one high dose litter were found to have
2 kinked tails. Dams were said to have shown altered
3 respiration and weight gain, but the data were not
4 presented.
5 In a two-generation rat reproductive toxicity
6 study conducted by the drinking water route and
7 described by US EPA and Ryan et al., 2001, at the
8 highest concentration of 5,000 ppm, postnatal day 0
9 litter weights were found to be decreased for both
10 generations. Maternal animals at this concentration
11 showed reductions in water and feed consumption, as well
12 as in body weight and weight gain.
13 Turning to male reproductive toxicity, no human
14 data were identified pertaining to the reproductivity
15 toxicity of phenol in human men.
16 So moving along to the animal data, in the
17 two-generation reproductive toxicity study described
18 previously, no effects were observed on mating or
19 fertility of the male rats exposed to phenol.
20 F1 males of the 5,000 group showed an increase
21 in age at preputial separation, which was accompanied by
22 a significant decrease in body weight at the age of
23 preputial separation.
24 Prostate weights of F1 males were significantly
25 reduced at all concentrations of phenol. Body weights

1 were significantly reduced only in the 5,000 ppm group.
2 Relative prostate weight showed a significant decrease
3 at the lower phenol concentration of 1,000 ppm.
4 Water and feed consumption were significantly
5 reduced in the 5,000 ppm F1 males at most of the time
6 points throughout the study.
7 In another study, Bulsiewicz gave phenol by
8 gavage to mice of both sexes for five generations.
9 There were dose-dependent increases in the frequency of
10 chromosomal changes in spermatogonia and primary
11 spermatocytes. Mortality was increased with the high
12 dose of 640 milligrams per kilogram of phenol, and three
13 males had to be sacrificed moribund.
14 Germ cell preparations from these moribund
15 males showed no primary or secondary spermatocytes,
16 spermatids or spermatozoa. At the same time, these
17 animals showed a relative increase in the number of
18 proliferating spermatogonia.
19 Turning to female reproductive toxicity, as
20 noted previously with the slide on human data pertaining
21 to developmental toxicity, the Hernberg study of 1,047
22 Finnish registry pregnancies did not indicate meaningful
23 associations between maternal exposures to disinfectants
24 and the occurrence of congenital defects.
25 Also as discussed previously, the Axelsonn

1 study of pregnant laboratory workers found a relative
2 risk for miscarriage among solvent-exposed pregnancies
3 of 1.31 with a 95 percent confidence interval of 0.89 to
4 1.91.
5 Perinatal death rates and malformation
6 frequency did not different between groups. Pregnancy
7 outcome was normal in the five individuals who
8 specifically reported phenol exposures.
9 Eight papers published in the Polish language
10 reported on aspects of placental structure and
11 histopathology for women believed to have had high
12 environmental exposures to aromatic hydrocarbons,
13 including phenol, and who also showed excessive levels
14 of phenol in their urine as compared to women from an
15 area that was considered to be nonthreatened. Placentas
16 from the women having high environmental exposures
17 showed changes consistent with impairment of placental
18 function.
19 In the two-generation rat reproductive toxicity
20 described previously, females given the highest
21 concentration of 5,000 ppm phenol in their drinking
22 water showed reduced water consumption as well as
23 reduced feed consumption at some time points. Body
24 weight and gestational weight gain were also reduced.
25 Phenol exposure had no effect on mating or

1 fertility. Estrous cycle length did not differ among
2 treated groups for either the P1 or F1 generations.
3 F1 females of the 5,000 ppm group showed a
4 significantly increased age at the time of vaginal
5 opening accompanied by decreased body weight at the time
6 of vaginal opening.
7 Concentration-dependent significant decrease in
8 absolute and relative uterine weights evident at all
9 concentrations on phenol.
10 As described previously for developmental
11 toxicity, the Research Triangle Institute completed
12 pilot and full-scale develop -- standard developmental
13 toxicity studies by the gavage route of exposure for
14 both rats and mice, and these studies have some data
15 relevant to female reproductive toxicity.
16 In the rat pilot study, maternal mortality was
17 in excess of ten percent at doses of 160 milligrams per
18 kilogram. Pregnancy rates at term were reduced at doses
19 of 160 milligrams per kilogram or higher. There were no
20 effects on implantation frequency, resorption frequency
21 or fetal viability.
22 In the full-scale rat study, which used a high
23 dose of 120 milligrams per kilogram, there was no effect
24 on pregnancy rate at term and no clear dose-dependent
25 effect on resorption frequency, nor was there

1 significant evidence for maternal toxicity.
2 Doses for the mouse pilot study ranged from 100
3 to 400 milligrams per kilogram. There were no effects
4 on implantation frequency or the number of live fetuses
5 per litter. There were increased resorptions and
6 nonlive fetuses seen at 230 and 260 milligrams per
7 kilogram.
8 The -- I'm sorry. I lost my spot here. Okay.
9 The full-scale study used a high dose at 280 milligrams
10 per kilogram, there were no effects on pregnancy rate,
11 implantation frequency or fetal viability. Because it
12 says the same thing as the pilot study.
13 Dams showed increased mortality at 280
14 milligrams per kilogram with survivors showing decreased
15 body weights and weight gain.
16 Argus Laboratories conducted pilot and
17 full-scale developmental toxicities in the rat by the
18 gavage route of exposure. Doses for the pilot study
19 ranged from 60 to 360 milligrams per kilogram with no
20 significant changes reported. The full study used a
21 high dose of 360 milligrams per kilogram and no
22 reproductive effects were reported.
23 And just to finish up with a quick summary,
24 reduced fetal or birth weight was the most commonly
25 reported effect in the developmental toxicity studies

1 where animals were exposed in utero.
2 In one study conducted in rats, statistically
3 significant decreases in mean fetal weights were
4 reported in the absence of evidence for statistically
5 significant treatment-related maternal toxicity.
6 In other rat and mouse studies, decreases in
7 fetal or birth weights, and in some cases malformations
8 were observed at doses of phenol that also resulted in
9 decreased maternal weights. Effects on viability have
10 also been reported in the presence or absence of
11 co-occurring maternal toxicity.
12 For male reproductive effects, in a
13 two-generation drinking water study in rats, significant
14 decreases in water and feed consumption and body weight
15 at the high concentration were accompanied by reductions
16 in absolute weight of nonreproductive and reproductive
17 organs, including seminal vesicles, testes and
18 epididymides. When considered relative to body weight,
19 changes in these organs were not statistically
20 significant.
21 Absolute prostate weights were significantly
22 reduced at all three test concentrations of phenol, and
23 relative prostate weight was significantly reduced at
24 the middle phenol concentration.
25 Age at preputial separation was significantly

1 delayed for the high concentration group and body weight
2 at the time of preputial separation was significantly
3 reduced.
4 One study reported dose-dependent chromosomal
5 aberrations in spermatogonia and primary spermatocytes
6 of male mice treated by gavage with a solution of phenol
7 in water. The frequency of these aberrations was
8 reported to increase with successive generations.
9 For female reproduction, in a two-generation
10 rat drinking water study, fluid consumption was
11 consistently reduced for females at the high
12 concentration group.
13 Feed consumption and weight gain of F1 females
14 were only sporadically affected by the high
15 concentration of phenol, though body weights were
16 significantly reduced.
17 There were no effects on fertility or
18 reproductive function, but age at vaginal opening was
19 delayed and weight at the time of vaginal opening was
20 significantly decreased.
21 Both absolute and relative uterine weights were
22 significantly decreased at all test concentrations of
23 phenol.
24 And that concludes my presentation, so I'd be
25 happy to take any questions.

1 DR. ROBERTS: Do you know what the -- for the
2 F1s in the repro study with the delayed sexual
3 maturation, how small were those F1 offspring at the
4 time that they started exposure directly?
5 DR. CAMPBELL: Oh, gosh, I don't know the
6 answer to that off the top of my head. I could dig it
7 out. That would take --
8 DR. ROBERTS: From a ballpark standpoint, were
9 they about 80ish percent of the control group?
10 DR. CAMPBELL: You know, I wouldn't like to say
11 because I really don't remember.
12 DR. ROBERTS: Okay.
13 DR. CAMPBELL: At the break I can -- you know,
14 I've got all the studies here, so you could take a look
15 at that.
16 DR. ROBERTS: All right, I'll come over and
17 check that. Thank you.
18 DR. SAMUELS: I also have a question. I'm
19 confused about the body weight per litter measure in
20 Table 4 of the HID. All of the other tables with
21 mean -- sorry --
22 DR. CAMPBELL: Table 4?
23 DR. SAMUELS: Table 4 on page 16 of the HID,
24 which reports birth weight per litter, I believe.
25 DR. CAMPBELL: That just means that it's --

1 DR. SAMUELS: Body weight --
2 DR. CAMPBELL: Let me make sure that I
3 understand your question. Body weight --
4 DR. SAMUELS: The --
5 DR. CAMPBELL: It just means that they've
6 organized the data on a per litter basis. I mean, that
7 is normally standard procedure, but if -- you know, if
8 the other ones, the tables don't specify, it's because
9 it wasn't clear from what was reported in the study how
10 they did it.
11 DR. SAMUELS: Well, the other tables show mean
12 fetal weight per litter and the units -- and all have
13 consistent units of about three to four grams, and
14 this -- and the units here and the numbers here are very
15 different. Mice versus rats --
16 DR. CAMPBELL: Yeah.
17 DR. SAMUELS: -- that's difference? I -- thank
18 you.
19 DR. ROBERTS: Mice are typically about a gram
20 at time of sacrifice in the developmental study.
21 DR. SAMUELS: But these are -- you can answer a
22 question --
23 DR. CAMPBELL: I'm still confused about what
24 the question is.
25 DR. SAMUELS: Okay, that's the question. The

1 numbers were so different for the --
2 DR. CAMPBELL: Oh, why are the numbers
3 different?
4 DR. SAMUELS: For the body -- for the weight.
5 DR. CAMPBELL: Yeah, that would be mice and
6 rats. Okay. Sorry.
7 DR. SAMUELS: All right. This -- I'll just
8 stop there.
9 DR. SHIONO: I have a question for the staff.
10 In the Axelsonn paper, they refer to three
11 previous studies of miscarriage in laboratory workers.
12 Were you able to review those studies or were they
13 relevant at all?
14 DR. CAMPBELL: We have to check that because
15 I -- you know, I don't remember and neither does my
16 colleague off the top of our heads.
17 DR. SHIONO: Okay.
18 DR. CAMPBELL: I'm not sure why we wouldn't,
19 you know, if they were relevant.
20 DR. JONES: The placental studies, which I
21 notice you don't comment on on your summary, do you put
22 any -- do you think they're significant at all?
23 DR. CAMPBELL: That's kind of asking for an
24 opinion which I don't, you know, really want to do --
25 DR. JONES: It doesn't make much sense --

1 DR. CAMPBELL: I mean, they're there for you
2 all to consider what kind of weight you want to put on
3 them.
4 DR. JONES: Yeah, they look pretty worthless to
5 me. I mean, I can't even -- I don't even agree with the
6 conclusions that they make from the studies.
7 Do you, Dottie?
8 DR. BURK: Well, you know -- I don't know. I
9 mean, I agree that perhaps some of the changes that they
10 found would be consistent with functional effects, but
11 the problem is we don't have any direct link of exposure
12 to phenol specifically to those things. So that's why
13 it's hard for me to put much weight on those studies.
14 DR. JONES: Would you consider them, just as a
15 matter of interest, female reproductive studies or
16 developmental toxicity in the fetus, the placenta being
17 the fetus?
18 DR. BURK: That's a good question, but it seems
19 to me that there's always this sort of overlap between
20 developmental and female that it's sometimes -- it's
21 hard for me to figure which category things go in, if
22 not both.
23 But as far as the criteria that we wrote, I
24 think, many years ago, we put placental function under
25 female reproductive toxicity, and I guess I think of it

1 that way. But, you're right, it is -- it's --
2 DR. JONES: Well, not only that --
3 DR. BURK: -- part of the fetus too.
4 DR. JONES: -- but yet there really is the
5 histology of the placenta and the gross morphology of
6 the placenta; not the function of the placenta. They
7 make a conclusion --
8 DR. BURK: Yeah, but you can't conclude that,
9 no.
10 DR. JONES: But you really can't do that.
11 Are -- are all of the human epidemiologic
12 studies, or the very few human epidemiologic studies
13 that you have quoted in terms of developmental toxicity,
14 studies that really have focused on phenol, or are they
15 organic solvents studies that look at a variety of
16 different organic solvents, one of which was phenol?
17 DR. CAMPBELL: Yeah. I mean, the latter. I
18 don't think you're going to find people who are just
19 exposed to phenol in the absence of other --
20 DR. JONES: Yeah, I think --
21 DR. CAMPBELL: -- solvents.
22 DR. JONES: -- probably I should mention,
23 although I don't mean to be picky, there is a paper in
24 the Journal of the American Medical Association which
25 was published just really recently -- not that recent --

1 1999, which has been the focus of some lawsuits, and
2 that's why I bring it up, which is entitled, "Pregnancy
3 Outcome Following Gestational Exposures to Organic
4 Solvents," one of which is phenol, and they show a
5 markedly increased relative risk huge for major
6 structural malformations associated with -- with organic
7 solvent use.
8 Now, I bring the paper up for a couple reasons,
9 but not the least of which is that it's a paper which is
10 really very poorly designed, and the conclusions in the
11 paper, I think, are very wrong. And, in fact, I know
12 about it because I wrote a commentary on the paper.
13 But I think that it's -- it is clearly an
14 issue, it's clearly been quoted frequently, it clearly
15 is getting out there. And, as I say, lawsuits are based
16 upon the paper, none that I know a jury awarded anything
17 for, but I just bring it up to you as something that I
18 think should go in the report.
19 DR. KAUFMAN: Just to elaborate, most of the
20 human studies do include multiple exposures. They are
21 listed as organic solvents.
22 I -- if my memory serves me correctly, the
23 articles cited in the Axelsonn study also don't
24 specify -- the articles that Dr. Shiono was referring to
25 that were referenced in that article don't cite phenol

1 exposure specifically.
2 And one of our criteria was that we were
3 reviewing articles that specifically mentioned phenol
4 exposure because, otherwise, organic solvents include
5 quite a number of substances.
6 So that is the problem, to -- to actually
7 identify that the woman was exposed to phenol at some
8 point.
9 DR. JONES: Yeah, well, that certainly is one
10 of the huge problems of these studies anyway. You don't
11 know what the woman was exposed to you, you don't know
12 when she was exposed to it, you don't know the
13 concentration.
14 You don't know, in the vast majority of cases,
15 much about these large retrospective epidemiologic
16 studies as they relate to the organic solvents, so it's
17 a bear to really look at and to interpret.
18 DR. SHIONO: Yeah, I also agree with the
19 staff's assessment about the human studies that you
20 they're -- you really can't come to any clear
21 conclusions about the relationship between phenol and
22 reproductive outcomes in humans. So I agree with your
23 comments and study.
24 CHAIRPERSON MILLER: I think we're getting to
25 the point where we need to take a break for our court --

1 stenographer. She's probably needing about a 10,
2 15-minute break at this point, and so we should adjourn
3 to 11:45 where we can pick up our discussion of phenol.
4 (Recess taken.)
5 CHAIRPERSON MILLER: I think we're ready to
6 continue our discussion.
7 OEHHA staff have informed me that some of the
8 questions that were asked earlier they've been able to
9 come up with some responses. So if you'd like to
10 reply.
11 DR. KAUFMAN: Hello, yes, I'm Dr. Farla
12 Kaufman.
13 Just to reiterate, those studies that were
14 mentioned, as I stated, the exposures were not
15 specifically to phenol as we know. They were --
16 especially in the Axelsonn study. They were asking
17 about occupations, specifically work in a laboratory.
18 They didn't make any effort to assess exposure to
19 specific chemicals or substances.
20 In terms of the mother risk study in JAMA that
21 Dr. Jones brought up, again, we have the issue of not
22 being able to assess exposure to specific chemicals.
23 They were asking people about their occupations and then
24 assuming they were exposed to certain substances.
25 Would you like me to comment any further? No.

1 Okay. Thank you.
2 CHAIRPERSON MILLER: Well, this is the
3 opportunity for our committee to discuss each of the
4 reproductive endpoints. So we'll start with
5 developmental endpoints for phenol.
6 DR. KEEN: I certainly can open up the
7 comments. As I look at the literature and also hear the
8 presentations, I'm struck by two observations.
9 The first is, if you look at typical ladder
10 studies where care has been taken to assess if maternal
11 toxicity's occurring as judged by a number of variables
12 ranging from reduced food intake to reduced maternal
13 weight gain, my impression of the literature is that you
14 do not see fetal abnormalities or fetal effects prior to
15 when you see evidence of maternal toxicity.
16 It's a -- a rather consistent thread across
17 many of the papers is that doses have been used which
18 caused -- I would call rather robust maternal toxicity,
19 so it's not just reductions in food intake but clear
20 clinical signs of toxicity such as tremoring, malaise,
21 et cetera.
22 So, in my opinion, those don't argue very
23 forcefully for this being a direct developmental
24 toxicant.
25 In the use cases where it's a little equivocal

1 as to whether or not there was maternal toxicity, the
2 data aren't there to really review because in some of
3 the earlier studies, for example, the food intake data
4 was not collected on a regular basis and there's not
5 comments as to what visual inspection of the dams were.
6 So as I view the literature, I'm left with a
7 sense that clearly this is an agent at very high
8 concentrations can induce toxicity. When that occurs,
9 there is, I think, very good evidence it can affect the
10 litter. But in the absence of that toxicity, I see no
11 consistent effects of the phenol.
12 CHAIRPERSON MILLER: What's the relevance of
13 kinked tails as in the Kavlock study?
14 DR. KEEN: Kinked tails sometimes are in the
15 eye of the beholder, it's been my experience. There are
16 some laboratories that seem to find them with great
17 regularity and frequency; other laboratories which
18 barely even comment on them.
19 I am not aware of any studies that, in the
20 absence of other sorts of malformations, that the kinked
21 tails actually signify anything, and that's why many
22 people do not report them unless it's extremely high
23 frequencies.
24 DR. ROBERTS: I think the only thing I can add
25 to that is in a -- sort of a study designed along the

1 lines of developmental neurotox, there were some kinked
2 tails observed at birth that disappeared postnatally.
3 DR. SAMUELS: One of the criticisms of the
4 RTI study, which claimed an effect on fetal weight in
5 the absence of maternal toxicity was that the control
6 group had an unusually high fetal weight, but I actually
7 think that -- and Dr. Murray emphasized this and it was
8 reported in the HID -- I think the criticism was
9 misplaced.
10 I imagine that there was variability in prior
11 control groups and that, indeed, this particular group
12 was at the high end of the range of individual control
13 means for prior studies.
14 But the fact that it was higher than the
15 overall mean for the control groups doesn't impress me
16 at all, and much was made of the fact that it was higher
17 than the 95 -- end of the 95 percent confidence interval
18 for the mean of all of the controls; whereas, the
19 relevant question is: How does it look in comparison to
20 the range of individual means of the control groups?
21 So I didn't see that as -- if controls were
22 quite variable, then a high value might not be so
23 unusual, and even though it -- it was certainly higher
24 than the overall mean. So that was not a definitive
25 argument except that it was an unusual study compared to

1 other studies.
2 DR. KEEN: Yeah, I certainly would agree with
3 your assessment. You have noted I did not comment on
4 that. I don't find that a particularly persuasive
5 argument.
6 I'm more swayed by looking at the data in
7 totality; that if I'm looking for consistency, I do not
8 see a consistent effect on body weights or fetal
9 weights, you know, independent of signs of maternal
10 toxicity.
11 DR. SAMUELS: The absence of maternal
12 toxicity --
13 DR. KEEN: Right.
14 DR. SAMUELS: -- claimed for that study is
15 what makes it problematic to me.
16 DR. KEEN: Yeah.
17 DR. SHIONO: I'm hoping for some discussion
18 about the RTI 1983 study on the -- it looks like
19 significantly increased malfor -- malformed fetuses at
20 virtually all dose levels. Can we have some discussion
21 on this and some help in interpretation, particularly
22 about the quality of these studies?
23 I'm a little bit puzzled about potentially why
24 these different studies don't show consistent results,
25 and it could -- I don't know, but it -- could it perhaps

1 be the quality on how the studies were done?
2 DR. ROBERTS: You're referring to the mouse
3 study?
4 DR. SHIONO: Right.
5 DR. ROBERTS: The mouse range finder, I should
6 say?
7 DR. SHIONO: RTI, 1983, B.
8 DR. ROBERTS: Okay. Where the table is on Page
9 16, Table 4, is that the one, looking at the individual
10 data?
11 What they comment on in here is -- and what
12 I've checked off in my notes and correct me I've -- if
13 somebody notes an error -- they didn't have any
14 malformations in the control group or the 100. They did
15 have them at 200, 230, 260, 300 and 400 and cleft palate
16 was the most commonly observed type of malformation.
17 Mice when stressed tend to -- that tends to be
18 the malformation finding. And, in fact, in inhalation
19 studies where narcosis can be induced, there's an
20 association between the level that causes narcosis and
21 the offspring having an increased incidence of cleft
22 palate. It's not a perfect correlation, but it's a
23 rather common finding and it's a rather common
24 malformation in mice.
25 With the group sizes that they have of -- well,

1 the control group was 27 litters, but only between 15
2 and 3 across those levels. I don't make a lot out of
3 the range finding study on the mice.
4 And on the -- on Page 18, Table 6 refers to the
5 main study in mice. They indicate an apparent but not
6 statistically significant trend for increasing frequency
7 of cleft palate with increasing dose. It's possible
8 that -- and it certainly looks to me like 8 out of 214
9 would be a level that's -- that is caused by exposure,
10 but I am not convinced that it's not related or could
11 not be secondary to the maternal stress.
12 There were some papers -- very old papers, but
13 nicely done, that looked at stress in mice and found
14 that that, without any agent, could cause an increase in
15 cleft palate.
16 DR. SHIONO: But wouldn't we expect all the
17 mice to be stressed equally? So why would that one
18 group have a different level of stress to have an
19 increase in cleft palate?
20 DR. ROBERTS: I wouldn't expect them to be
21 equally stressed because, as you increase the dose, you
22 increase the effects upon the animal.
23 And in terms of variability, my graduate work
24 actually looked at cleft palate in mice, and at
25 something that was about the ED50 for cleft palate in

1 mice, you could have a litter that had none at all and a
2 litter that was a hundred 100 percent. So it can vary
3 quite a bit.
4 DR. KEEN: I think it's worth noting that in
5 the dose ranging, I mean, the 200s, when they first
6 started seeing it, and they even comment that the
7 animals going -- were showing tremors at that point,
8 that's a pretty serious sign of maternal toxicity.
9 And the -- I think what's critical is the 100
10 dose where the statement is there was no evidence of
11 maternal toxicity even using the standards and there
12 were no malformations.
13 DR. SAMUELS: I have a question which I'll just
14 throw out to my fellow committee members.
15 In the introduction to the phenol document, it
16 was stated that a human dose of 70 milligrams per
17 kilogram was -- had been lethal, and the LD50 for animal
18 studies -- for laboratory animals unstated ranged for --
19 from 300 to 600 milligram per kilogram of body weight.
20 And the doses that were reported in all of
21 these studies then strike me as quite high in comparison
22 to these numbers, even though obviously the animal
23 strains might have varied and we weren't killing off 50
24 percent of the animals even at the higher doses.
25 But it still seemed to me something -- it also

1 struck me that many of these doses, as you say, induced
2 real signs of mortality in that they seemed to have been
3 too high toxicity.
4 DR. KEEN: I mean, just to -- I think this is
5 one reason why I really dwell on the maternal toxicity
6 in this particular chemical, in particular, because I
7 read it the same way.
8 I was impressed at how high these doses are. I
9 mean, if we're now literally operating around what would
10 be the near lethal or lethal doses for humans in some
11 cases, then that suggests that it's -- it's not
12 surprising we're -- you know, tremors are being reported
13 as well as other signs of clinical sort of disease in
14 these animals. Typically, we would be fairly cautious
15 about interpreting the effects then on the embryo or
16 fetus.
17 CHAIRPERSON MILLER: Steve, can you comment
18 about the use of statistical trend tests --
19 DR. SAMUELS: Well --
20 CHAIRPERSON MILLER: -- about this?
21 DR. SAMUELS: -- there's a -- many of my
22 colleagues have believed that if you have a number of
23 dose groups, that only those that are individually
24 statistically significant compared to the control group
25 are those in which there is an effect.

1 Whereas, if you imagine that there is really a
2 dose response as toxicological principles would assume,
3 then -- and we happen to observe that dose response even
4 though the -- an individual group closer to the control
5 is not clearly statistically different from it, the
6 trend test will be sensitive to the dose response in a
7 way that a comparison of a single group will not.
8 So the trend test generally is more powerful
9 and will find an association because it uses the
10 information that there is, indeed, a dose response. It
11 doesn't attempt to ascertain whether which particular
12 groups that made up the group are -- are definitely
13 different from the control.
14 And you could argue that, if you believe in the
15 idea of the dose response, putting fewer animals in each
16 group but having more groups so that you can get an idea
17 of the range of the response curve is actually more
18 valuable, even though you sacrifice the ability to say
19 exactly what is the no effect level or the low observed
20 effect level.
21 So the design of these studies is a
22 compromise. So I do pay attention to trends, and I see
23 those.
24 DR. ROBERTS: Along those same lines, if one
25 looks at that Table 1, which is a range finder, and

1 Table 2, which is the main study for it, and I guess
2 Table 6, which is the main study for mice, if you
3 eliminated the levels that had significant maternal
4 mortality, and I believe that that would be 160 and
5 above on Table 1, just the 120 milligram per kilogram
6 per day on Table 2 and the 280 milligram per kilogram
7 per day on Table 6 --
8 DR. SAMUELS: There's no trend.
9 DR. ROBERTS: -- there's no trend?
10 DR. SAMUELS: There's no trend. I thought the
11 same about Table 1 in which, once I eliminated the
12 highest groups, there was no trend apparent.
13 So it is also possible to use the information
14 from the trend test which in this case depended on the
15 two groups which -- with the highest dose primarily, to
16 claim there is a trend where there isn't.
17 So one has to be quite careful, I mean, about
18 the interpretation of this as about any data. So I
19 agree with you.
20 DR. ROBERTS: Okay.
21 DR. SAMUELS: I am more impressed by the trend
22 test when I see that, indeed, there is an apparent
23 trend, though clearly that could occur by chance as
24 well. So I --
25 DR. ROBERTS: Thank you.

1 DR. SAMUELS: And I did the same thing as you
2 probably did and cut off those high dose studies and
3 then looked to see what happened in the lower dose
4 groups; and if it actually continued the same trend into
5 the higher dose groups that, to me, was some evidence of
6 an association.
7 DR. ROBERTS: Thank you.
8 CHAIRPERSON MILLER: Additional comments?
9 We'll move on to female.
10 DR. HOBEL: Yeah, I just want to make a
11 comment.
12 I thought that the initial comment about the
13 higher doses that are studied result in a tremendous
14 amount of maternal toxicity, and whether or not it's
15 appropriate to be doing studies when you use such high
16 doses that results in maternal toxicity, but it adds to
17 this trend effect.
18 I mean, I think that's one reason for designing
19 the studies with these high doses is to -- to make
20 certain you are observing or not observing a trend
21 effect. You need that higher dose in order to make that
22 observation.
23 DR. ROBERTS: You don't mind if I comment
24 further that the practical standpoint, when someone
25 conducts a study for a notification or submission, you

1 run the range finder because one of the things you're
2 looking for specifically is to get maternal toxicity
3 because, if you are in -- if you have no maternal
4 toxicity occur in your study and no developmental
5 effects, it's considered an invalid study, you haven't
6 gone high enough.
7 And so sometimes in the range finding study
8 you'll go up to a level -- it -- it will be designed to
9 go up to a level that's expected to cause toxicity; and
10 if it's excessive for animal welfare reasons, you may
11 not continue that dose level.
12 It almost is fortuitous that you end up getting
13 a trend from that. And, hopefully, though, it helps you
14 design a better guideline study so that you can reach
15 the level where you're having some amount of maternal
16 effect so it's clear that you're getting absorption and
17 you've reached about a maximum tolerated dose under
18 those circumstances but you haven't ended up
19 compromising your ability to look at the fetal
20 parameters.
21 CHAIRPERSON MILLER: Female reproductive
22 toxicity. Comments?
23 DR. SAMUELS: There's the Bulsiewicz study on
24 chromosomal damage in sperm, and that study wasn't
25 given -- and the critique of the study in the HID was

1 that it had been discounted in a review because of
2 concerns about the protocol and about the criteria for
3 diagnosing the sperm abnormalities.
4 However, as I look at that study, it's hard to
5 think of any bias in -- in criteria for identifying
6 that -- those abnormalities that would explain away the
7 large dose-related differences in -- what table are we
8 looking at -- Table 16, which is on Page 43 of the HID.
9 So I'm wondering if my fellow committee members
10 have a thought on that. Marion, you've probably looked
11 at more sperm than I have so --
12 CHAIRPERSON MILLER: I thought the numbers were
13 quite striking, and there was a dose-response
14 relationship, according to the data set, and it seemed
15 to be increased with generational time as well, as you
16 moved across generations.
17 I believe the study, in terms of how they did
18 it, they seemed to do a good study. I'm not quite sure
19 how to interpret it in that there were limitations to
20 the study and whether or not -- and we're unaware of
21 those limitations because I don't have access to the
22 text of the information, I don't know how detailed the
23 methods were.
24 And Alan, who brought up the fact that it was
25 inconclusive in his review of phenol, he clearly felt

1 the same, that he didn't have the tool set to really
2 evaluate what their data was saying.
3 But I think there's a dose response, there is a
4 generational effect that is intriguing that I'd like to
5 see more information about.
6 But to balance that, NTP did do a dominant
7 lethal that they didn't -- is unpublished -- again, we
8 don't have the details of that study -- but they did do
9 a dominant lethal study and saw no effect.
10 So now we've got the NTP with this dominant
11 lethal study, chromosomal aberrations which are really
12 quite significant but at very high dose levels.
13 Relatively speaking, at -- 640 milligrams per kilogram
14 is not a small amount.
15 So I must admit -- we moved from female to
16 male, that's fine, we can talk about male first --
17 DR. SAMUELS: I'm sorry. I thought that's what
18 you asked about. I apologize.
19 CHAIRPERSON MILLER: That's fine.
20 And it's -- as with many of these chemicals,
21 there's a gray area, and there's going to be a judgment
22 when we come to make our decision, is -- how heavily do
23 we weight the positive data with the chromosomal
24 aberration study versus the negative data with the
25 dominant lethal study?

1 DR. ROBERTS: Marion.
2 CHAIRPERSON MILLER: Yes.
3 DR. ROBERTS: Would you -- I guess this is a
4 question looking at rats and mice because this study on
5 the -- the NTP study were both done in mice, so we have
6 one positive looking like a dose response and one
7 reported as negative.
8 The rat reproduction study looked at sperm
9 parameters, also, and came out clean. Would you expect
10 that -- this much discordance between the rat and mouse?
11 CHAIRPERSON MILLER: Well, the NTP study in the
12 mouse is not discordant with what -- in the rat is not
13 discordant with the mouse study. What is discordant is
14 the chromosomal aberration study.
15 I did have a question. It said in the document
16 that they used light microscopy in a times 1,500
17 magnification and I know that won't work, so I'm not
18 quite sure of what they were doing.
19 Other comments about male reproductive
20 effects?
21 DR. BURK: Well, as long as we're on the male,
22 I would like to hear from some other panel members about
23 the effects in the EPA study, the increased age at
24 preputial separation and the decreased absolute prostate
25 weights. Biological significance? Is it strictly

1 related to weights, so forth?
2 CHAIRPERSON MILLER: I wasn't -- the prostate
3 weights did look like they were lower at dose levels
4 where you weren't seeing major effects in body weight,
5 and, in particular, in the F1 generation at 1,000 parts
6 per million, and even though there was no statistical
7 significance, the 2000 -- 200 parts per million value,
8 it does look like it's beginning to decrease.
9 However, at the 5,000 parts per million
10 prostate, we went back to control levels. So that
11 didn't seem consistent with a return to control values
12 after -- and two dose levels at the intermediate point
13 where they started to decline.
14 The other thing is the prostate is an
15 androgen-dependent organ; and when you start seeing
16 decreased prostate weights, you'd expect to also see
17 decreased epididymal weights since that's also an
18 androgen-dependent organ. So I was surprised at only
19 the prostrate going down without an epididymal effect.
20 In fact, the same epididymis increased at the
21 higher dose levels. Epididymal weight significantly
22 increased in these F1 animals at the 5,000 parts per
23 million.
24 With regard to the preputial separation as a
25 marker for adolescence, I read the review with interest

1 and -- suggesting that there's a separation of body
2 weight and any of the times of onsets of adolescent
3 markers.
4 Clearly there was decreased body weights in
5 these same animals that had the increased time to
6 preputial separation.
7 I think some comment could be made in light of
8 the female reproductive tox where the vaginal opening
9 also seemed delayed and associated with a decrease in
10 body weight.
11 DR. ROBERTS: I'd like to comment on the sexual
12 maturation part because, actually, I think it could be
13 considered a developmental endpoint as well.
14 I know of agents that will accelerate one sex
15 and delay another or alter one sex and have no effect on
16 the other, but I don't know of any chemical agents that
17 will delay both male and females and to -- roughly to
18 the same extent.
19 I've been involved with some female pubital
20 assays in rats and some male assays as well and looked
21 at these -- the degree of difference in age that's seen
22 at 5,000 ppm is definitely a fairly strong measure.
23 But you also have to think about they're also
24 smaller still, I should say -- not just simply
25 smaller -- but smaller still at the time that they have

1 sexual maturation occur, which means that at the time
2 that the control normal group was doing it, they're even
3 smaller than that. And that's why I pose the question
4 of what, say, percent of control body weight were the F1
5 offspring?
6 I don't think there's a perfect time, but if
7 there are animals that are smaller, have stunted growth,
8 I think it does cause a delay. At some point, though,
9 sexual maturation is going to occur. And in this case
10 it has occurred in both of them at a later age, still
11 though, at a smaller size.
12 So that -- and if someone knows of an agent
13 that would delay in both sexes, that would tend to sway
14 me towards thinking that this could be directly exposure
15 related.
16 In the absence of that, I'm more inclined to
17 think that it's more of a side effect of systemic
18 toxicity that is making the animals be smaller; and when
19 these animals matured or went through their pre-mating
20 exposure, they did end up apparently having normal
21 fertility in the next generation.
22 CHAIRPERSON MILLER: We have one public
23 comment; and if there's no further immediate discussion
24 within the panel, we have an opportunity to discuss this
25 again before we make our decision after we've heard the

1 public comment. So if we're in an agreement, would that
2 seem like -- moving along --
3 And so we have a blue card from Jay Murray
4 and -- who's going to talk about phenol, and he
5 represents a group that he'll have to explain what the
6 abbreviations mean.
7 DR. MURRAY: Thank you, Dr. Miller, members of
8 the committee. My name's Jay Murray, and I'm -- I will
9 explain what those letters mean. I'm speaking on behalf
10 of the Phenol Panel of the American Chemistry Council
11 and the Phenol Task Group of the Consumer Healthcare
12 Products Association. And in the written comments that
13 I submitted you'll see a footnote that explains who both
14 of those are and who they represent.
15 I also have some slides, and I brought
16 copies -- can you hear me okay? Is that better? I'm
17 normally not this quiet. I also have handouts of the
18 slides which, if this helps, I'll give to you.
19 Now, I've got about, as you can see from the
20 handout, about 14 slides. I'll try and move through
21 this quickly because I recognize it's getting close to
22 lunchtime.
23 So what I'm going to do is summarize the
24 written comments that you all received from me a couple
25 of weeks ago as well as present a little bit of new

1 information.
2 Next slide. By way of background, phenol was
3 considered for listing a number of years ago through the
4 authoritative bodies mechanism, and it was -- it was not
5 listed, obviously.
6 And I mention that so you know that, in effect,
7 the reason phenol is before you today is because US EPA
8 has not formally identified phenol as a developmental or
9 reproductive toxicant.
10 You have a very thorough comprehensive Hazard
11 Identification Document which I'm going to abbreviate as
12 HID. You just received an excellent presentation from
13 Dr. Campbell, and that makes my job a lot easier.
14 There are some things on these sides that I
15 think I can go through pretty quickly because you've
16 already heard it from others this morning.
17 In my written comments, I concluded that there
18 was insufficient evidence that phenol causes
19 developmental or reproductive toxicity. I said that
20 there was no meaningful evidence in humans and little
21 evidence in animals even at toxic doses.
22 And I'm going to go through and kind of
23 re-summarize some of that, but what's new is I'm also
24 going to present you with an evaluation by Dr. Anthony
25 Scialli.

1 I know many of you are familiar with Dr.
2 Scialli. He is a Professor of Obstetrics and Gynecology
3 at Georgetown University Medical Center. He's also a
4 past President of the Teratology Society and founding
5 editor of the Journal of Reproductive Toxicology.
6 And some of the slides at the end of my
7 presentation are essentially going to summarize his
8 evaluation of the phenol data; and when I get to that,
9 I'll explain the background and how it came about that
10 he did that.
11 Next slide. The epidemiologic studies, you've
12 already heard a lot about this and discussed it a lot.
13 I agree with the conclusions that Dr. Campbell reached.
14 I also agree with a lot of the comments that have
15 already been covered here.
16 I think the bottom line is that the human
17 studies are limited. They have, you know, a number
18 of -- first, there aren't that many. The ones that
19 there are have limitations. One of the most notable
20 limitations is -- several people have already noted --
21 is the multiple exposure to chemicals.
22 And so -- and my conclusion is that the studies
23 are insufficient to demonstrate that phenol causes
24 reproductive or developmental toxicity.
25 Next slide. Of some interest are -- is the

1 series of studies out of Poland and -- that has been
2 presented to you already that show an association
3 between histologic abnormalities in the placenta and
4 residence near petro chemical plants.
5 And as you've already recognized, part of the
6 difficulty with that study is it was not truly a study
7 of phenol; it was a study of people who lived near a
8 heavily-industrialized area and they may have been
9 exposed to many different substances.
10 That study used urinary phenols as a proxy for
11 exposure. The problem with that is that urinary phenols
12 is not a specific marker for exposure to phenol. There
13 are a lot of aromatic hydrocarbons that will metabolize
14 to phenol. And I think Dr. Campbell, when she was
15 summarizing this study, said that this was essentially a
16 study of exposure to aromatic hydrocarbons.
17 So I think that's all I'm going to say on
18 epidemiology.
19 And on the next slide we'll shift to animal
20 studies. This slide highlights the fact that there
21 are -- although there are a lot of studies of phenol,
22 there are really three key developmental studies, you've
23 talked about them, and then there's the two-generation
24 reproduction study.
25 And if we go to the next slide, this slide

1 looks a lot like a slide that Dr. Campbell presented.
2 What I did is I went to the Hazard Identification
3 Document to look at what endpoints they flagged. These
4 were the endpoints of potential concern.
5 And what I'm going to do in the subsequent
6 slides is -- I've got a slide on, I think, each of these
7 endpoints that summarizes the data. So my presentation
8 will be a little different from Dr. Campbell's because
9 Dr. Campbell went through by study. I'm going to go
10 through by endpoint and give you that perspective.
11 Next slide. Fetal body weight. There are
12 several studies, as you've already discussed, that show
13 at high levels of exposure phenol decrease -- is
14 associated with a decrease in fetal body weight.
15 And in all those studies but one it was seen in
16 the presence of maternal toxicity -- enough maternal
17 toxicity to explain the decrease in fetal body weight.
18 The exception, which you've discussed already,
19 is the RTI rat study where the original conclusions of
20 the study was that a decrease in fetal body weight was
21 seen in the absence of maternal toxicity. You realize
22 that that's inconsistent with the results of the other
23 studies.
24 And I've, in my written comments, highlighted a
25 number of potential concerns with the RTI rat study, and

1 let me just highlight them very quickly.
2 The first, which I agree is the most important,
3 is there were few measurements of maternal toxicity in
4 that study. That study was published -- and it was --
5 and the report came out in '83. The study was actually
6 done in 1980, and it was a time when many labs did not
7 take a lot of measurements in maternal toxicity and, as
8 someone's already noted, there was no food consumption,
9 water consumption data in that study.
10 They did do maternal body weights, but the
11 intervals were further apart than they would be for
12 studies that we do today. So perhaps one of the reasons
13 why they did not see maternal toxicity is that the study
14 wasn't designed to look very hard for maternal
15 toxicity.
16 The second point is at one point during the
17 study a number -- an unspecified number of animals were
18 found without feed. Anyone who's done animal studies
19 for very long knows that these sorts of things go wrong
20 occasionally, and -- but having an unknown number of
21 animals, not clear which groups they were in, not clear
22 how long they were out of food represents a possible
23 confounding factor both for maternal body weight and for
24 fetal body weight.
25 The last point on this slide is -- is the

1 control fetuses were unusually heavy, and -- and I
2 respect the comments that Dr. Samuels made on that. I
3 fact, I think we're probably in agreement. I don't
4 consider that to be a definitive observation either.
5 What I was trying to do is explain why it's
6 possible that -- you know, that we have this study where
7 they saw a decrease in fetal body weight without any
8 apparent maternal toxicity.
9 Next slide. And there was one other point I
10 wanted to mention on this same thing, and that's litter
11 size. This table is actually a table I created in the
12 written comments so you've seen it before.
13 And what it is showing, if you look at -- if
14 you look at the mean live fetuses per litter, the litter
15 size at the high dose you can see was higher than it was
16 for the controls, about one-and-a-half fetuses on
17 average larger. That was not statistically
18 significant.
19 And there was some discussion in the Hazard
20 Identification Document about what role that might or
21 might not play, and one of the comments was that it --
22 it was not -- you know, since it was not a statistically
23 significant difference between the high dose and
24 controls, that it may not be a factor.
25 But part of the diff -- it's not quite that

1 simple, and the reason it's not that simple is the
2 variability in those two parameters. Litter size, fetal
3 body weight is very different, so it's tougher to show a
4 statistically significant difference in mean litter
5 size.
6 The co-efficient of variance is about
7 four-and-a-half percent for litter size in this study,
8 and the co-efficient of variance for fetal body weight
9 in this study is about one percent.
10 So -- and then the last line is something that
11 I did, it's the mean litter weight, which is the product
12 of litter size and fetal body weight, and you can see at
13 the high dose that, you know, there really isn't a
14 difference at least in mean litter weight which, again,
15 by itself doesn't prove anything, but it suggests that
16 litter size may, indeed, have played a role in the
17 decreased fetal body weight.
18 Next slide. Viability. There was no
19 consistent effect on viability, as has already been
20 noted. I agree with Dr. Campbell's characterization of
21 the studies.
22 The RTI study showed a statistically
23 significant increase in resorptions at 30 and 60
24 milligrams per kilogram, but not at 120. No effect on
25 resorptions on the Argus rat developmental tox study,

1 even though they used a higher dose than the RTI study.
2 And no effect on resorptions in the mouse study even at
3 maternally toxic or even lethal doses.
4 Next slide. The third endpoint of potential
5 concern was cleft palate, and you've already discussed
6 this. You've discussed the apparent trend, and I want
7 to go back and just emphasize one point that was
8 discussed is -- and I think it was in response to Dr.
9 Shiono's question about, you know, maternal toxicity and
10 why stress at that dose -- at the high dose.
11 That was a very high dose in that mouse
12 developmental toxicity study. Produced death in 4 out
13 of 36 dams. Also, a lot of the classical symptoms of
14 acute toxicity of phenol: ataxia, tremors, lethargy,
15 irritability. These are the classic symptoms you see,
16 you know, that precede CNS death from phenol.
17 So not surprising to me that at the high dose
18 in this study there was an incidence of cleft palate of
19 8 out of 214 fetuses. Not at all surprising.
20 The authors, as you know, didn't attribute the
21 cleft palate to phenol. They said it's more likely the
22 result of maternal stress.
23 Next slide. So that was developmental
24 toxicity. Now I want to talk a little bit about
25 reproductive toxicity, and I have one slide here, and a

1 lot of this you've heard so I'll go fast.
2 Phenol had no effect on male or female
3 fertility or reproductive capacity, no histologic
4 effects on reproductive organs or accessory sex organs,
5 no effect on sperm count, motility, morphology.
6 You were talking about the Bulsiewicz study
7 before, and I recognize that's a mouse study and this is
8 a rat study, but unusual for a compound to have the kind
9 of effects that were seen in the Bulsiewicz study and
10 not have an effect on fertility and not have it show up
11 in sperm counts or anything else.
12 Interestingly, there actually was a
13 statistically significant effect on sperm count in
14 the -- in the two-generation reproduction study and that
15 was a statistically significant increase which the
16 authors discounted and said that's not due to phenol.
17 There were the delays in the markers of onset
18 of puberty and changes in uterine and prostate weights,
19 which you all have discussed before.
20 Dr. Roberts, you asked a question about the
21 body weights of the pups, and in the break we pulled out
22 the study, and I've got the pup weights at the high dose
23 compared to controls, and I'll just -- I'll pick day 21,
24 these are day 21 pups, to give you an idea of the
25 magnitude.

1 The mean pup weight was about 41 grams at the
2 high dose. It was 58 grams in the controls. So it's
3 about a 30 percent difference in pup weight by day 21.
4 And they were smaller from birth. That just continued
5 out through that period.
6 So -- and that's the reason why the authors of
7 the study, as well as US EPA, when it reviewed this
8 study, because -- this study was done because US EPA
9 said there are no, you know, good reproduction studies
10 of phenol that we can rely on. That's the reason it was
11 done in the first place.
12 And they looked at it and they said, well, more
13 likely than not the -- all of these effects are due to
14 reduced water consumption in that study. There's a
15 taste aversion problem with phenol in drinking water,
16 and this was a drinking water study.
17 So the animals were not drinking as much water,
18 they didn't gain weight compared to -- to the controls
19 in the animals receiving lesser doses, and it's not
20 surprising then that the fetuses weighed 30 percent less
21 than the control -- the fetuses and the pups weighed --
22 you know, the pups weighed 30 percent less by the 21st
23 day after birth.
24 And that's consistent -- you know, there are
25 other studies that show if you restrict food consumption

1 and restrict fetal -- or pup development that much, it's
2 consistent with the kind of changes that have been
3 observed here.
4 And I think the important thing to remember is
5 sort of the first three bullets on this slide. I can't
6 think of a reproductive toxicant that doesn't do at
7 least one of those things.
8 Next slide. Well, I mentioned the evaluation
9 by Dr. Scialli at the outset, and -- and you all have a
10 copy of Dr. Scialli's letter, and the background on this
11 is I asked Dr. Scialli to evaluate the data on phenol.
12 I did it recently because I wanted a reality check, and
13 I wanted to make sure there was nothing that I missed.
14 So what he had to go on is he had a copy of
15 the Hazard Identification Document, the same one that
16 you have, and he had all the original studies and the
17 literature, and my only instructions to him was I told
18 him I wanted his honest, objective opinion.
19 I did tell him what the Prop 65 listing
20 criteria were, but I said put it -- just evaluate it the
21 way you would evaluate the phenol data, put it in your
22 own words, and -- and more than anything, I need your
23 honest evaluation because -- and my reason for that is,
24 if I missed the boat, I wanted to know it before --
25 before today.

1 So his main conclusions -- and his conclusions
2 are mostly in the first paragraph and in the final
3 paragraphs of the letter.
4 He said: It is not my scientific judgment that
5 phenol has been clearly shown to cause reproductive or
6 developmental toxicity.
7 I think in the last paragraph he said: In
8 conclusion, evaluation of dose response curves suggests
9 that effects on development are secondary to impaired
10 maternal health and are not due primarily to phenol
11 exposures.
12 Well, in the letter, it -- it is very clear
13 that Dr. Scialli did his own independent evaluation of
14 those studies, and he focused very heavily on the animal
15 studies in his letter.
16 If you go to the next slide, this is a slide
17 that I prepared using information in Dr. Scialli's
18 evaluation. One of the things he did is he went back
19 and calculated a benchmark dose for the endpoints of
20 maternal weight gain and fetal body weight for each of
21 the studies that you see here.
22 And, as you know, the benchmark dose represents
23 an alternative approach to evaluating data. Traditional
24 method is to look at the NOEL and see how the NOEL for
25 maternal toxicity compares to the NOEL for developmental

1 toxicity.
2 One of the disadvantages of that approach is --
3 as we all know, is that the NOEL is a function of the
4 dose levels that get picked for the study, it can't be
5 something in between; whereas, the benchmark dose allows
6 extrapolation for an effect in between. You can define
7 the benchmark dose as a five percent or a ten percent
8 decrease in fetal body weight.
9 And the numbers that you're seeing here are Dr.
10 Scialli's estimates of the 95 percent confidence limit
11 of the dose that produces a ten percent decrease in
12 either maternal weight gain or fetal body weight.
13 And as you look at the table, the point of the
14 table is that the benchmark dose estimates show that you
15 would expect to see an effect on maternal weight gain
16 before you would see an effect on fetal body weight,
17 with one exception, and that is the RTI main rat study,
18 which we've discussed.
19 And Dr. Scialli looked at that study, he
20 noticed -- he raised -- I think the way he put it, he
21 said he had limited confidence in these figures because
22 of the concerns about the food issue in that study.
23 But this was how he approached looking at the
24 issue of: What's the role of maternal toxicity?
25 Because -- you know, when I looked at it, I was looking

1 at NOELs and trying to compare across studies.
2 What he did is he simply accepted that these
3 are real effects in every single one of these studies,
4 estimated a benchmark dose, and what these results
5 provide is additional support for the effect on fetal
6 body weight being secondary to maternal body weight.
7 Last slide. So in summary, the epidemiologic
8 studies do not provide meaningful evidence. The animal
9 studies provide insufficient evidence. There was
10 limited evidence in the presence of significant maternal
11 toxicity.
12 And, in my opinion, phenol has not been clearly
13 shown through scientifically valid testing, according to
14 generally-accepted principles, to cause developmental or
15 reproductive toxicity.
16 You know what my opinion is. You know that Dr.
17 Scialli came to a similar opinion. You know that US EPA
18 and other authoritative bodies have not identified
19 phenol as a developmental or reproductive toxicant.
20 But the opinion that really matters today is
21 yours. You all will have to decide whether it's been
22 clearly shown to cause developmental or reproductive
23 toxicity.
24 Thank you. I'd be happy to answer any
25 questions you may have.

1 DR. JONES: Jay, what do you do with the
2 chromosome abnormalities?
3 DR. MURRAY: You know, I'll be honest with you.
4 I'm not sure what to make of the chromosome
5 abnormalities. And one of the -- after listening to
6 your discussion, I wish I had gone back and looked at
7 the original article. I have -- I have not seen the
8 original article, and I don't know if that was part of
9 your package.
10 I looked quickly to see where it was published
11 to see if I could read it very quickly, and it's not --
12 you know, it's in a Polish journal that I'm not familiar
13 with, so I don't know how good the studies are.
14 I wonder about, you know, why did they see the
15 effects in that study? And why not a similarly -- some
16 evidence of a similar effect in the two-generation
17 reproduction study.
18 The two-gen repro study was done in the late
19 '90s, it was done at Itry (phonetic) and, you know, you
20 saw it in Dr. Campbell's slides as the Ryan et al.
21 study, Dr. Ryan and a number of people published that
22 study, so I know that that's a good study.
23 I don't know enough about the study where they
24 saw the chromosomal effects to know whether it was a
25 good study or not. So I wish I knew more to be able to

1 answer your question.
2 CHAIRPERSON MILLER: Any more questions for Dr.
3 Murray?
4 DR. JONES: Did Dr. Scialli comment on the
5 chromosomal --
6 DR. MURRAY: He did not.
7 DR. JONES: Yeah.
8 DR. MURRAY: He did not. And, you know, I --
9 he must have seen the reference to the studies because
10 he read the Hazard Identification Document, but he
11 didn't for some -- obviously, for some reason he didn't
12 think it was important enough to comment on. But I
13 don't -- I'd have to speculate on that, and I really --
14 I don't know why he chose not to comment on it.
15 But the one thing I can tell you for sure is
16 that that letter is exactly as -- as he wrote it.
17 DR. DENTON: Yes, I wanted to ask George if he
18 could just maybe elaborate a bit on why phenol is before
19 the committee today.
20 DR. ALEXEEFF: Just as a clarification, as
21 indicated on -- in the preface, the -- phenol had been
22 prioritized high, and it was on that basis, using our
23 prioritization procedure, that it was selected for
24 developing an HID and brought to this committee.
25 CHAIRPERSON MILLER: Other discussion of the

1 committee with our three reproductive endpoints? I know
2 we started discussing, but we have heard additional
3 discussion; so in light of that, any additional things
4 we want to talk about?
5 DR. ROBERTS: I'd like to make just one
6 comment. In some of the comments that were written and
7 expressed about the water consumption and food
8 consumption, there are effects on that on phenol.
9 I guess I'm not as convinced that phenol
10 doesn't have toxicity at those levels of exposure
11 separate from simply having less water consumption.
12 I'm not personally convinced that it's
13 reproductive toxicity, but the expression that all of
14 the effects that are seen are directly due to reduced
15 water consumption, I'm -- I just want to indicate I'm
16 not convinced that it isn't also an agent that has
17 toxicity at some of those exposure levels as well.
18 DR. SHIONO: It seems to me like -- you know,
19 all studies are not perfect, but there seems to be --
20 when you take a step back and look at all the data
21 that's presented, that there's a troubling amount of
22 information here that does seem to me that shows there
23 is a relationship between phenol and some of these
24 reproductive outcomes.
25 The decreased fetal weight with the

1 significance for trend in two studies, although, you
2 know, one was the pilot and one was the main. There's
3 that really troubling increase in malformations,
4 chromosomal changes in the male, uterine weight
5 decreases and resorptions.
6 So this is troubling to me. It's not clean
7 here. You can't explain it all away. And I know people
8 are -- I'm a little bit concerned, and so I wanted to
9 express that.
10 DR. JONES: What were the malformations you
11 were referring to?
12 DR. SHIONO: They don't say specifically. They
13 just say a significant increase in malformed fetuses.
14 That's in the RTI b study, the main study.
15 DR. ROBERTS: Mouse or rat?
16 DR. SHIONO: Mice.
17 DR. ROBERTS: Okay.
18 DR. KEEN: I just want to say, it's not that I
19 disagree with your concern, but I think I still look at
20 the data in totality and it suggests when you have
21 maternal toxicity with this agent, which certainly does
22 occur at certain levels, then there's number of untoward
23 effects on reproduction.
24 But that's -- in theory, we're supposed to be
25 able to say: Are there effects that are independent of

1 maternal toxicity? And I think that's where there seems
2 to be a lack of evidence, in my opinion.
3 This does not mean that this is not an agent
4 that doesn't have the potential for representing a risk,
5 you know, to the mother at high enough -- if at a high
6 enough concentration.
7 DR. SHIONO: But in my reading of the data it
8 shows that some of the lower levels show problems with
9 fetal weight and malformations. So it's hard to just
10 dismiss the studies because they were using too high a
11 dose. And the test for trends also corroborate that
12 feeling that there may be something going on, even at
13 the lower levels.
14 DR. JONES: Carl, are you -- do you feel able
15 at all to comment about this -- the chromosomal thing
16 in --
17 DR. KEEN: I studiously have stayed away from
18 it, it seemed like.
19 DR. JONES: I noticed that.
20 DR. KEEN: A piece of information that I
21 confess I find troubling -- and I wish I had the
22 opportunity to look in detail at the paper. I'm less
23 concerned about some of the other -- I mean, the trend
24 analysis, if I -- if one removes the groups where
25 maternal toxicity is there, as I look at the trend

1 analysis, it falls apart. Therefore, I don't see it as
2 a valid sort of analysis in this particular case.
3 That's my interpretation.
4 But the chromosomal abnormalities -- I
5 sometimes perhaps will seize on small points. But as
6 Marion pointed out, at least when it was referred to us,
7 the methodology wouldn't necessarily work, so one has --
8 has to look at it, I think, fairly carefully.
9 DR. ROBERTS: The only thing I have to compare
10 it to is cyclophosphamide, which is used as a positive
11 control in some genetic toxicity studies. It will cause
12 chromosomal aberrations, and it's also a very strong
13 teratogen.
14 So, again, I -- it just pushes me back towards
15 I don't know what to make of it because what I know
16 happens with a material -- a chemical that will cause
17 chromosomal aberrations, then goes on to cause very
18 strong malformations, here we have one that appears to
19 be causing a significant number of chromosomal
20 aberrations and doesn't seem to be doing that in the
21 mouse study, which would keep it in the same species.
22 DR. JONES: Well, is this -- are sperm looked
23 at for chromosomal abnormalities in the usual -- in the
24 usual situation? Isn't this a rather unique thing to be
25 doing?

1 CHAIRPERSON MILLER: I've seen many studies
2 looking at aneuploidy and using fish type approaches for
3 looking for chromosomal damage to sperm. I wouldn't
4 necessarily say it's part of a routine screen and --
5 DR. JONES: So is that -- so is it ever found?
6 CHAIRPERSON MILLER: Yes.
7 DR. JONES: In cyclophosphamide? In things
8 that are not a problem?
9 CHAIRPERSON MILLER: Benomyl, carbendazime
10 (phonetic), aneuploidy.
11 DR. JONES: And I don't know about the -- I
12 don't know about those agents in terms of what effect
13 they are felt to have on male reproductive toxicity.
14 CHAIRPERSON MILLER: In microtubule function
15 potentially.
16 DR. JONES: So a problem?
17 CHAIRPERSON MILLER: What we're really talking
18 about is that you have chromosomal aberrations in one
19 study and we have not a consistent response in the other
20 studies that would be --
21 DR. JONES: Consistent.
22 CHAIRPERSON MILLER: -- consistent with that --
23 the levels of chromosomal aberrations. That's my
24 problem.
25 DR. JONES: Okay.

1 CHAIRPERSON MILLER: It's a non sequitur.
2 DR. JONES: Okay.
3 CHAIRPERSON MILLER: I mean, you would have
4 expected to have seen something in those whole animal
5 studies --
6 DR. JONES: Okay.
7 CHAIRPERSON MILLER: -- if there was -- if
8 there was chromosomal --
9 DR. JONES: That was real?
10 CHAIRPERSON MILLER: Yes.
11 DR. JONES: And we don't know enough about the
12 study in terms of its methodology, et cetera?
13 CHAIRPERSON MILLER: And that is something
14 that's slightly frustrating because I looked up where
15 that publication was, and it was from a journal I didn't
16 recognize and from Warsaw, I think, so I couldn't have
17 access to that data set, and maybe that was something
18 that we -- I should have requested ahead of time is to
19 get access to the data so that we could actually see
20 what was there. Because these articles are not easy to
21 track down from those sources.
22 AUDIENCE MEMBER: We've got it right here.
23 DR. JONES: Ah, it's sitting on that chair
24 right there.
25 AUDIENCE MEMBER: It's in Polish.

1 CHAIRPERSON MILLER: Can we look at the paper
2 briefly?
3 DR. KEEN: You know, it's -- again, it could
4 easily be a typographical error in the manuscript, but
5 given the fact that they are saying that they did this
6 work with a light microscopy at 1500 magnification, that
7 would be very unusual.
8 So it would make me have to weigh this
9 relatively lightly because if it is a typographical
10 error, one, of course, wonders about its accuracy.
11 The methodologies here are not the typical
12 methodologies that would be employed in most
13 laboratories today, so I think we should be cautious not
14 to overinterpret this paper. That would be my
15 opinion at this point.
16 DR. HOBEL: I have a question. Is this
17 chemical being considered by the Carcinogen Committee,
18 also?
19 DR. ALEXEEFF: No, it is not.
20 DR. HOBEL: And why not?
21 DR. ALEXEEFF: Well, we have separate
22 prioritization procedures for the two committees based
23 upon the information available.
24 But I don't think -- US EPA has considered it,
25 and they considered it not classifiable for

1 carcinogenicity. So I don't think there's any
2 substantial evidence -- do you have any more to add on
3 that? There isn't really. Yeah, I don't think there's
4 any -- yeah, it's a promoter, but it doesn't seem to
5 have any actual carcinogenic activity.
6 DR. HOBEL: Because I was wondering, isn't this
7 used in clinical medicine as a sclerosing agent for
8 hemorrhoids and also for varicose veins? And,
9 therefore, exposure through that mechanism may be
10 important in older people.
11 I think it is used in clinical medicine as a
12 sclerosing agent. Does anyone have any information
13 about that?
14 DR. CAMPBELL: It is in over-the-counter
15 medications like throat sprays for sore throats and
16 things like that. I don't know about the specific
17 applications you mentioned. I didn't run across that
18 but, you know, I wasn't really looking in detail.
19 CHAIRPERSON MILLER: I think EPA classified it
20 as a D chemical, which means unknown, there's no real
21 data to support it being classified as a carcinogen.
22 And with all this chromosomal damage and DNA
23 damage that must be going on, I'm surprised, I think
24 that's another inconsistency.
25 DR. ROBERTS: One other one I notice is that

1 the translation information on Page 41 indicates that
2 the top dose was about 640 milligrams per kilogram body
3 weight, which exceeds the range given to us for an oral
4 LD50 value, and yet none of these mice were reported to
5 have died until their third generation. So this strain
6 may be very different from the ones that we're used to.
7 DR. KLONOFF-COHEN: I just wanted to ask some
8 clarification. The difficulty for me is that there
9 isn't a lot of epidemiologic -- any information.
10 And when I look particularly at the summaries
11 for the -- if we go for the female and the male studies,
12 I'm hearing a lot of what sounds like limitations from
13 study to study. And yet I'm still queasy about voting
14 because of the fact that there seems to be, to me, what
15 looks like some male and female reproductive issues that
16 I don't feel comfortable about.
17 So is there somebody that could start with the
18 female and -- not go through study by study, but just
19 basically in the summary box sort of addressing the RTI
20 studies, for instance, to try to convince me?
21 DR. KEEN: I can't do that, but just to quickly
22 answer something that Linda asked, the strain for this
23 study was the Porten strain, which is apparently an
24 inbred culture that they have. I'm unfamiliar -- I've
25 never heard of the Porten strain before.

1 DR. ROBERTS: I haven't either.
2 CHAIRPERSON MILLER: So the female reproductive
3 endpoints were the markers for puberty, which is
4 delayed -- there was a delay in vaginal opening, and the
5 change in the uterine weight. Those were the two major
6 changes that I could see that had something that was
7 potentially statistically significant.
8 I think the adolescence marker, it suffers from
9 the same -- it's the same kind of concept approach as
10 the -- for -- in the male and the female since we have a
11 delay in preputial development.
12 Now, they were both associated with smaller
13 body weights, and there was a discussion about what's
14 the role of body weight in timing for onset of markers
15 for adolescence.
16 I'm -- another question could be, are these
17 male or female reproductive toxicants or developmental
18 toxicants if you look at it as a developmental endpoint.
19 You could even pull it out of the definition of male or
20 female reproductive toxicity.
21 My own looking at the prostate numbers, I
22 didn't feel it was totally compelling, even though the
23 lower dose levels did have an effect on prostate weight.
24 The fact that the higher dose level did return to
25 control I wasn't so convinced by.

1 The uterine weights, I don't think, came
2 back -- I don't think they returned to control values
3 and -- but there was no change in pathology which, if
4 something had been going on, I would have expected to
5 have seen differences in follicle counts or whatever.
6 There's -- these are gray areas, but there's
7 arguments of pros and cons, and we're trying to put it
8 all into some sort of perspective to come up with a
9 reasonable vote.
10 DR. ROBERTS: I don't know if this addresses
11 the sexual maturation very well. The positive control
12 agents that I've seen in, say, female, at the dose
13 levels that would cause a four -- three- or four-day
14 acceleration at least would be dose levels that would
15 pretty much leave the animals in constant estrous and
16 they wouldn't have litters. There wouldn't be a second
17 generation.
18 I don't know if that's directly applicable to
19 something that would cause that much of a delay or not,
20 but to have -- have this large a delay and then not have
21 any impact upon the number of animals that were pregnant
22 or any of the estrocyclicity endpoints suggests to me
23 it's not a direct reproductive effect on it.
24 DR. SAMUELS: May I ask -- excuse me. May I
25 ask for a clarification?

1 I just realized that in the text referring to
2 the Bulsiewicz study, the high dose that was referred to
3 was eight grams per liter per group, but in the table
4 that the dose is referred to is eight milligrams per
5 liter.
6 CHAIRPERSON MILLER: The -- it was in --
7 DR. SAMUELS: Which one -- which is it?
8 CHAIRPERSON MILLER: It was in the drinking
9 water at a concentration of two mills of solution --
10 they were given two mills of the solution of phenol --
11 DR. CAMPBELL: This says eight grams.
12 DR. KEEN: It's eight grams.
13 DR. SAMUELS: Okay.
14 CHAIRPERSON MILLER: -- at point naught -- .08,
15 .8 and 8 grams per liter, but they give them two mills
16 of eight grams per liter. They're not -- it's not in
17 the drinking water. They're giving it as a bolus.
18 DR. ROBERTS: I can see why that's confusing
19 because if you look at the concentrations corresponding
20 to the doses on Page 41, it's 6.4, 64 and 640; whereas,
21 we have it going from .08, .8 or 8, and the .8 is shown
22 as milligrams per liter, and the next one up is shown as
23 grams per liter, which would be a thousand-fold
24 increase.
25 Is it clear from that paper which it is?

1 CHAIRPERSON MILLER: It's two mills -- it's all
2 three dose levels, .08, .8 and 8.
3 DR. ROBERTS: Grams?
4 CHAIRPERSON MILLER: Grams per liter, two mills
5 of that, by gavage.
6 DR. SAMUELS: So the labeling of the tables as
7 milligrams per liter is simply incorrect, okay.
8 DR. ALEXEEFF: Well, there appears to be the
9 same -- George Alexeeff -- appears to be the same error
10 in the actual paper. So that's the problem.
11 CHAIRPERSON MILLER: So thinking of the dose
12 level on a per kilogram basis. If you say they're
13 getting two mills of an eight gram per liter solution,
14 they're getting around 400 milligrams per kilogram if
15 they're 40 gram mice -- which they may or may not be --
16 somewhere in that range.
17 Other comments or are we ready to vote? We
18 are, okay.
19 So my question of the committee -- questions
20 are: Has phenol been clearly shown through
21 scientifically valid testing, according to
22 generally-accepted principles, to cause developmental
23 toxicity?
24 All those voting yes, please raise your hand.
25 All those voting no, please raise your hand.

1 DR. DENTON: Dr. Shiono, we can't -- can you
2 not --
3 DR. SHIONO: I'm abstaining. I don't know.
4 There's not enough information here for me to make a
5 decision.
6 CHAIRPERSON MILLER: Eight committee members
7 voted no.
8 All those abstaining, please raise your hand.
9 And one committee member abstained.
10 Has phenol been clearly shown through
11 scientifically valid testing, according to
12 generally-accepted principles to, cause female
13 reproductive toxicity?
14 All those voting yes, please raise your hand.
15 All those voting no, please raise your hand.
16 Nine committee members.
17 All those abstaining -- no abstentions.
18 Has phenol been clearly shown through
19 scientifically valid testing, according to
20 generally-accepted principles, to cause male
21 reproductive toxicity?
22 All those voting yes, please raise your hand.
23 All those voting no, please raise your hand.
24 Nine committee members. And no abstentions.
25 Thank you.

1 So I hope that we can keep you away from lunch
2 for just a little bit longer. We have some updates on
3 the agenda -- or should we have lunch? I think they're
4 going to be very short so, Cynthia, if you would like to
5 go ahead.
6 MS. OSHITA: Okay, this will be very brief.
7 As is my usual practice, I report to you on the
8 status of the chemical listings by the administrative
9 listing mechanisms, and since the last DART Committee
10 meeting in December of 2002, OEHHA has administratively
11 added three chemicals to the Proposition 65 chemical
12 list as known to cause cancer.
13 They were carbon black (airborne, unbound
14 particles of respirable size), strong inorganic acid
15 mists containing sulfuric acid and catechol.
16 A list of -- the current list is provided in
17 your binder of meeting materials.
18 Additionally, a public notice was published in
19 the California Regulatory Notice Register as well as
20 posted on the OEHHA website announcing the proposed
21 consideration of six chemicals for administrative
22 listing via the authoritative bodies mechanism.
23 And these six chemicals are now in the data
24 call-in phase. The public comment period will close on
25 November 25th, 2003. And a copy of the public notice is

1 also included in your meeting materials.
2 In terms of safe harbor level development,
3 OEHHA has continued work on developing the safe harbor
4 levels for chemicals already on the Proposition 65
5 chemical list.
6 And as you may recall, a "safe harbor level" is
7 the general term used to refer to the "no significant
8 risk levels" for carcinogens and the "maximum allowable
9 dose levels" for chemicals that cause reproductive
10 toxicity.
11 These levels are adopted in regulation and
12 assist interested parties in determining whether
13 warnings are required for exposures to listed chemicals
14 and whether discharges of those chemicals to sources of
15 drinking water are prohibited.
16 If an exposure can be shown to be less than the
17 regulatory level, the responsible person has a safe
18 harbor from the warning requirement and discharge
19 prohibition.
20 Since last December, OEHHA has adopted 20 safe
21 harbor levels, 5 MADLs and 15 NSRLs. A list of these
22 safe harbor levels is provided in your binder materials
23 as well in the September 2003 Proposition 65 Status
24 Report on Safe Harbor Levels. The newly added safe
25 harbor levels are underlined within the document.

1 On June 13th of this year, OEHHA initiated
2 another rulemaking package proposing to adopt 11 safe
3 harbor levels, 1 MADL and 10 NSRLs. A copy of the
4 Notice of Proposed Rulemaking is also in your
5 materials.
6 A public hearing was held on July 31st, 2003.
7 No written or oral comments were received on two of the
8 NSRLs, for benzene and bromoform, so OEHHA expects to
9 finalize the rulemaking package to formally adopt these
10 two levels into regulation in the very near future and
11 will complete the -- and continue the rulemaking process
12 for the remaining nine.
13 I have also been asked to give an update on
14 the perchlorate. As you recall at the last meeting of
15 the DART Committee on December 4th, the subject of
16 perchlorate was discussed in the context of its
17 consideration for expedited review. The request was
18 made by several public-interest groups.
19 The DART Committee requested OEHHA to take
20 perchlorate out of the usual prioritization process
21 order and to prepare a draft Hazard Identification
22 Document as resources were available.
23 In addition, the committee asked for a written
24 progress report in six months on the status of the
25 development of the Hazard Identification Document and

1 other regulatory actions involving perchlorate.
2 A written progress report was sent to the
3 committee members on July 17th, 2003 advising you of the
4 status of perchlorate. OEHHA is still awaiting the peer
5 reviewers comment on the Public Health Goal document on
6 perchlorate.
7 That's it.
8 CHAIRPERSON MILLER: Thank you.
9 DR. ALEXEEFF: Hello. The next item is about
10 the prioritization procedure.
11 Our current procedure for prioritizing
12 candidate chemicals came into effect in 1997. I'd like
13 to clarify for the committee that the procedure for
14 prioritizing chemicals is a policy and is not subject to
15 a regulation.
16 At the last Cancer Identification Committee in
17 December, the committee asked that we come up with an
18 alternative procedure that would better take into
19 account toxicity and exposure, and Dr. Mack appointed
20 two leads to discuss the issue with us.
21 Since prioritization also affects reproductive
22 toxicity, we contacted Dr. Miller and asked her to
23 appoint some leads as well, which she did.
24 We had three meetings where we discussed how
25 the current process works, the procedures used by other

1 organizations, and our plan is to see how we might
2 fine-tune the current prioritization process.
3 We plan to keep working with the
4 representatives of the committees and to submit any
5 proposed changes for public comment early next year.
6 CHAIRPERSON MILLER: Thank you, George.
7 I think we're coming to the end of our meeting;
8 and if there's no further questions, then Dr. Denton is
9 going to summarize our actions and present some closing
10 remarks.
11 DR. DENTON: The committee today had two
12 chemicals before it, propachlor and phenol.
13 The committee came to a unanimous decision not
14 to list propachlor as a reproductive or developmental
15 toxicant.
16 Regarding phenol, there was also a unanimous
17 decision not to list phenol for reproductive toxicity.
18 The committee concluded also -- or decided to recommend
19 not to list phenol for developmental toxicity, but here
20 the vote was eight members voting no and one member
21 abstaining.
22 I would like to close by thanking the members
23 of the audience for their attendance, the members of the
24 committee for their attention to these chemicals that we
25 have brought before them and for their actions and

activities as the State's qualified experts.

I'd also like to thank Ed Weil for being here today as our legal representative. And I'd also like to thank, finally, the members of my staff who have done, again, just an excellent -- an excellent job in preparing the documents and in seeing their -- following through in their responsibilities under Proposition 65, Lauren and George, Marlissa, Jim, Jim, Ling Hong, Farla and Mari, Poorni -- these individuals did not speak -- Cindy, Susan. It's a pleasure to be part of this group.

I also asked the staff this last year that we not have the meeting in December. So, as you see, we've had it in October. Of course, thinking at the time that what could be -- what could be stressful about October 2003?

Well, we all know what has been stressful about October 2003, but I do appreciate the work that's been done by my staff to have the meeting today.

So with that, that's all the comments I have, and I guess Marion will close the meeting.

CHAIRPERSON MILLER: I should just echo Joan's comments about OEHHA staff. I think this committee much appreciates the excellent documents that we receive for review.

1 So I think the meeting is adjourned.
2 (Proceedings concluded.)
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1 REPORTER'S CERTIFICATE

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4 STATE OF CALIFORNIA)
) ss.
5 COUNTY OF SACRAMENTO)

6

7 I, PHYLLIS MANK, certify that I was the
8 Official Court Reporter, that I reported in shorthand
9 writing the foregoing proceedings to the best of my
10 ability; that I thereafter caused my shorthand writing
11 to be reduced to typewriting, and the pages numbered 1
12 through 114, inclusive, constitute a complete, true and
13 correct record of said proceedings:

14

15 In witness whereof, I have subscribed this
16 certificate at Sacramento, California, on this 12th day
17 of November, 2003.

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20

PHYLLIS MANK, CSR No. 5093

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MICHAEL P. WALLS

VICE PRESIDENT

REGULATORY & TECHNICAL AFFAIRS

December 17, 2010

SENT VIA ELECTRONIC MAIL

Mr. John R. Williams
Washington State Department of Ecology
W2R HQ
P.O. Box 47775
Olympia, WA 98540-7775
jowi461@ecy.wa.gov

RE: American Chemistry Council Comments on Proposed WAC 173-334

Dear Mr. Williams:

The American Chemistry Council (ACC) appreciates the opportunity to comment on the Department of Ecologyôs (DOE or Department) WAC 173-334, proposed regulations to implement the Childrenôs Safe Products Act.[1] The safety of childrenôs products is of the utmost importance, and addressing the potential risks faced by children from possible exposure to chemicals is an important objective of the proposed regulations. Although ACC supports several concepts in the proposed regulations, there are several provisions that cause concern.

Presence Does Not Equate to Harm

ACC strongly agrees with the need to prioritize chemicals in commerce to identify those of potential concern. In the absence of prioritization, everything (or nothing) is a priority ï a result that has serious implications for the effective management of any regulatory system.

[1] ACC represents more than 140 leading companies engaged in the business of chemistry, including nearly 6,000 chemistry industry employees in Washington State. Our members apply the science of chemistry to make innovative products and services that make people's lives better, healthier, and safer. Our products are the foundation of virtually every industry, from medicines to fabrics, plastics to clean drinking water, cell phones to aircraft. ACC is committed to improved environmental, health, and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing.

In WAC 173-334-070, DOE clarifies that it will identify chemicals for inclusion in its list of chemicals of high concern to children (CHCCs) by determining whether a chemical meets both toxicity, persistence, or bioaccumulativity criteria *and* meets exposure criteria specified in the enacting legislation. ACC appreciates DOEôs recognition that the regulatory program must integrate hazard and exposure information to identify CHCCs. A robust prioritization process should utilize specific hazard and use/exposure criteria so that both governmental and industry resources are directed toward the greatest potential risks. For any chemical, natural, or synthetic, the degree of toxicity and the potential for harm is dependent upon the dose/exposure. Many government agencies, including the U.S. Environmental Protection Agency and the Centers for Disease Control readily acknowledge that the mere presence of a substanceð in our environment, in our bodies, or in our productsð does not necessarily mean there are potential exposures or the risk of harm. It is always a question of the thresholds at which there may be risk of harm, and existing risk assessment data can help fill this data need. To pave the way for a chemical reporting scheme that makes public health sense, therefore, ACC urges DOE to define ñpresence of a substanceò in the final regulations to mean presence at threshold levels.

In addition to this technical clarification, there are also communications issues that ACC requests that DOE address. ACC appreciates DOEôs accurate clarification in WAC 173-334-010 that ñ[r]eporting the presence of a CHCC does not establish that the product is harmful to human health.ò Despite this DOE admission, however, it is likely that the public will be confused as to what the CHCC list truly is, and what it is not. The proposed regulations are not clear about how and with whom the information contained in the notices will be shared. In ACCôs view, it is imperative that whenever DOE publishes or identifies the CHCC list or discusses the presence of CHCC substances in products, that DOE carefully communicate that the presence of a CHCC in a childrenôs product does not establish that a product is harmful to human health. Without communicating the CHCC list in context, the regulations will result in significant market effects for all noticed products, as consumers may understand the listing to be a regulatory decision that a product poses a risk of harm. It is inevitable that when a technical list such as the CHCC list is assembled, it will result in confusion as to what it actually means, and such confusion may unnecessarily drive safe products off Washington shelves.[2]

In short, DOE must be clear as to what the CHCC list is, and perhaps even more importantly, what it is *not*. This is essential to minimize premature product de-selection by consumers, retailers, and suppliers. Otherwise, the CHCC list becomes a blacklist by default. Under those circumstances, DOEôs proposed regulations would not serve the public health interests of the citizens of Washington state. Without plans to interpret whether these products pose real threats, the information will frighten people unnecessarily.

Along these lines, DOE may want to publicly clarify why many potentially dangerous ñtoysò have been excluded from the regulations. Section 1(3)(b) of the enacting legislation specifically excludes from the definition of ñchildrenôs productò slings and catapults, sets of darts with

[2] As Washington State Governor Christine O. Gregoire stated in her April 1, 2008 letter to the Washington House and Senate regarding the enacting legislation for WAC-173-334 (a partial veto letter), ñWithout careful implementation, this bill could adversely affect the availability of safe toys in our state, including important educational toys.ò ACC agrees.

metallic points, BB guns, pellet guns, air rifles, and pocket knives, for example. Without further clarification, the public may wrongly presume that the presence of CHCC substances in childrenôs products poses dangers that exceed those of these excluded items.

Additionally, DOE should explicitly state in its final regulations that those products already regulated under other Washington state law, or federal programs such as the Consumer Product Safety Improvement Act, Toxic Substances Control Act, Federal Insecticide Fungicide and Rodenticide Act, or by the Food and Drug Administration, for example, are not subject to DOEôs proposed regulations.

Intentional Addition to Children's Products vs. Naturally-Occurring Levels

It is unclear in both the enacting legislation and the proposed regulations whether *any* presence of a substance on the CHCC list must be reported if found to be within the identified concentration ranges, or whether only *intentional* additions of such substances are of interest. If DOE is interested in *any* presence, no matter how it came about, the Department must realize that trace contaminants may appear at levels requiring notice. ACC strongly urges DOE to clarify that its regulations apply only to intentional additions of CHCC chemicals.

ACC agrees that ñ[a] manufacturer of childrenôs products is responsible for knowing the amount of CHCCs in its childrenôs products and their componentsò (WAC 173-334-130(1)). It is possible, however, that unintentionally added ingredients (e.g., trace contaminants in public water supplies used in manufacturing or from shipping and transportation) may be able to be detected in some childrenôs products at levels above the *de minimis* levels being contemplated by DOE. Concerns regarding trace levels of contaminants arising in air, water, etc. should be the focus of appropriate environmental regulations for those media, and not these childrenôs products regulations.

***De Minimis* Level Must Be 1,000 ppm (0.1%)**

WAC 173-334-090 establishes a *de facto* minimum concentration level of 40 ppm (0.004%). ACC strongly supports DOEôs inclusion of a *de minimis* threshold, generally, but we urge DOE to set a threshold that is feasible for measurement of all potential CHCCs. We recommend 1,000 ppm (0.1%). This is a level consistent with the notification requirements established by the United Nationôs Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (*see* GHS 1.5.3.1.1 and Table 1.5.1). The GHS system has already been adopted by the United States Department of Transportation, and the level is consistent with the United States Occupational Safety & Health Administration hazard communication standards.[3] 0.1% should therefore be the smallest amount required for notice by DOE, as well. The final regulations should therefore not include WAC 173-334-090(1)(e)(i)-(ii), which contain the requirements to report ranges of equal to or more than 40 ppm but less than 200 ppm, and equal to or more than 200 ppm but less than 1,000 ppm.

[3] Additionally, a 1,000 ppm level is both technically and economically feasible.

It should be clear that the definition of a priority product includes presence of the chemical of concern above the *de minimis* level. A product containing a chemical of concern below the *de minimis* level should not be considered a priority product. For compliance and enforcement purposes, manufacturers should be expected to maintain records supporting the application of the *de minimis* threshold to their particular product.

The underlying legislation specifically states in Section 4(4) that notification is to include ñ[t]he amount of the chemical used in each unit of the product or product componentò and that ñ[t]he amount may be reported in ranges, rather than the exact amount.ò But the legislation does not prescribe what those concentration ranges are. In ACCôs view, DOE has clear legal authority to change 40 ppm to 1,000 ppm.

The legislation also bans childrenôs products or product components containing lead at more than 90 ppm and cadmium at more than 40 ppm. Additionally, it includes a possible restriction on childrenôs products or product components that contain lead at more than 40 ppm. The proposed CHCC list, however, includes far more substances than lead and cadmium. Beyond these substances, DOE has the authority to implement a *de minimis* reporting level of 1,000 ppm.

Food and Food Packaging Are Not Children's Products

Section 1(3)(a) of the legislation defines ñchildrenôs productò to include toys, childrenôs cosmetics and jewelry, child car seats, and products ñdesigned or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by childrenò. The section goes on to specifically list items that are not considered childrenôs products. Foods, food products, and food contact materials (the materials used to make food packaging) are addressed by federal statute and regulated by the federal Food and Drug Administration. They should therefore be excluded from the definition of ñchildrenôs productò.

This approach is also required by legislative intent. The Governorôs partial veto letter to the CSPA refers only to toys, car seats, and childrenôs products, as these product categories are understood by the Governor. We therefore recommend that the definition of ñchildrenôs productò expressly exempt foods and food additives (which includes food contact materials used to make food packaging) as approved by the U.S. Food and Drug Administration.

Manufacturers of Both Children's and Non-Children's Products

Clarification is needed on the tiered reporting due dates proposed in WAC 173-334-120. Specifically, when a company manufactures both childrenôs and non-childrenôs products, does it only need to consider the childrenôs products sales to determine what manufacturer category it is in? Or does DOE intend that ñannual aggregate gross salesò includes *all* products manufactured by a company, and not just childrenôs products?

Additionally, ACC strongly urges DOE to remove Product Tier 4 from proposed WAC 173-334-120(2). DOE indicates that reporting for Tier 4 (childrenôs products not intended for direct contact with the childôs skin or mouth, e.g., internal components) will be determined on a ñcase-

by-caseò basis, but it is difficult to understand what case could possibly warrant concern. Internal components are not likely to come into contact with children through reasonable and foreseeable means, and should be exempted from the reporting obligations of these regulations.

Protection of Confidential Business Information

In WAC 173-334-090(3), DOE explicitly states, ñIf a reporting party believes the information being provided is confidential business information (CBI), in whole or in part, it can request that the department treat the information as [CBI]é The department will use its established procedures to determine how it will handle the information.ò ACC commends DOE for recognizing the importance of protecting CBI and encourages the Department to do as much as it can to continue its efforts to protect American innovation and jobs by protecting legitimate CBI.

Delisting of Substances from the CHCC List

ACC commends DOE for including in its proposed regulations both a process for delisting an original CHCC substance (WAC 173-334-080), as well as intending ñto revise the CHCC list on a regular basisò (WAC 173-334-060(2)).

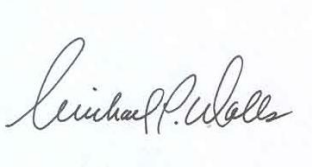
Quality of Scientific Information

The draft regulations require decisionmaking to be based on ñcredible scientific peer-reviewed information.ò WAC 173-334-070(c), 080(1)-(2). ACC supports this approach. We believe that the information relied upon by DOE must be of appropriate quality, replicable, and relevant to human health assessments. ACC therefore suggests that the phrase ñcredible scientific peer-reviewed informationò be modified to ñcredible and reliable scientific peer-reviewed literature.ò

* * * * *

We look forward to working with you and DOE on this rulemaking. If you have any questions, please contact me or Amy DuVall (amy_duvall@americanchemistry.com; 202.249.6415). Thank you in advance for considering our comments, as well as those of several ACC chemical-specific panels, which are being submitted under separate cover.

Sincerely,



Michael P. Walls
Vice President
Regulatory & Technical Affairs

Anthony R. Scialli, M.D., Professor
Department of Obstetrics and Gynecology
Georgetown University Medical Center
3800 Reservoir Road, N.W.
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October 9, 2003

Members of the DART Identification Committee
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1001 I Street, 19th Floor
Sacramento CA 95812-4010

I have been asked to review studies on possible reproductive and developmental effects of phenol, and to determine whether phenol has been clearly shown to cause reproductive or developmental toxicity. It is my scientific judgement that phenol has not been clearly shown to cause reproductive or developmental toxicity.

My training in reproductive and developmental consisted of a fellowship with Sergio E. Fabro, M.D., Ph.D., one of the early investigators of thalidomide embryopathy and co-developer of the Brown-Fabro score, used in whole embryo culture evaluation. I am Professor of Obstetrics and Gynecology at Georgetown University Medical Center in Washington, D.C., Director of the Reproductive Toxicology Center in Bethesda, Maryland, and Founding Editor of *Reproductive Toxicology*, a leading peer-reviewed journal in the field. I currently serve as Principal Investigator for the Center for the Evaluation of Risks to Human Reproductive, a project of the National Toxicology Program. I am a member and Past President of the Teratology Society, and a member of the Organization of Teratology Information Services, the Society of Toxicology, the American College of Toxicology, and the European Teratology Society, among other professional and academic associations.

My review of the literature included review of the draft Hazard Identification Document dated July 2003 from the Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency and the published and unpublished reports cited therein. These reports involve research performed with experimental animals and reports from human populations in Poland, with translations of these latter reports into English.

The reports from Poland show an association between histologic placental abnormalities and residence in a community that was contaminated by industrial activity. The use of urinary phenol concentration in these studies is taken as a proxy for exposure; however, the exposure cannot be concluded to have been solely to phenol. The presence of other chemical contamination in the community is likely, preventing the conclusion that phenol exposure is causally associated with the placental histologic abnormalities. There are no studies in humans showing that phenol causes reproductive or developmental toxicity.

My approach to the experimental animal studies involved consideration of the role of general toxicity in producing adverse reproductive effects. Fetal growth, for example, relies on the transfer of calories and nutrients from the pregnant animal to the conceptus. If maternal feed intake is decreased due to inappetence or inanition, conceptus growth would be expected to be vulnerable. As another example, fertility in males and females relies on release of hypothalamic gonadotropin-releasing hormone (GnRH). GnRH release is

inhibited by stress, mediated through opioidergic input from the periventricular region. If a chemical treatment produces generalized toxicity, a consequent decrease in GnRH and in reproductive function would not be unexpected. In these examples, the developmental and reproductive effects would be secondary phenomena, and not indicators of developmental or reproductive toxicity of the chemical under study.

It has been common in risk assessment activities to compare general toxicity and target organ toxicity by comparing no observed adverse effect levels (NOAELs) or lowest observed adverse effect levels (LOAELs) for representative endpoints. The NOAEL/LOAEL approach relies on the doses selected in the design of the study and does not take into consideration the shape of the dose-response curve. A more complete comparison of the dose-response curves for general toxicity endpoints and for developmental/reproductive endpoints may be preferable. One approach that has been promoted by the US Environmental Protection Agency is the benchmark dose calculation. The benchmark dose is calculated from a model that uses the entire dose-response curve and represents the exposure level expected to produce a predetermined effect level, whether or not that dose was an administered dose in the study under evaluation.

My evaluation of the phenol data base involved a comparison of benchmark doses for endpoints representing generalized, development, and reproductive toxicity. The software available from the US EPA (http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20167) was used to calculate the dose associated with the upper bound of the 95% confidence interval around a 10% effect level (abbreviated BDML). Consistent with the recommendations of the model developers, I used data sets where pairwise statistical significance had been identified for at least one dose, or for which a significant trend had been demonstrated. Thus, I did not use the developmental data set generated by Kavlock[1], which showed no statistically significant alteration in litter size, pup weight, perinatal loss, or litter biomass in spite of dose-related adverse effects on maternal weight gain, although this result is also consistent with my conclusion that phenol has not been clearly shown to cause reproductive or developmental toxicity.

My general findings were consistent with the conclusion that developmental and reproductive effects associated with phenol treatment occur in the face of maternal or adult toxicity and are consistent with being secondary to that toxicity, rather than due to developmental or reproductive toxic effects of phenol itself. My specific findings are as follows:

1. RTI rat developmental toxicology study[2]: In a pilot study, the administered phenol dose range was 0–250 mg/kg/day. The BDML for maternal weight gain (GD 6–15) was 24 mg/kg/day. For mean fetal weight/litter, the BDML was 242 mg/kg/day. Thus, modeling the dose–response curves for maternal weight gain and for fetal weight/litter predicted that minimal effects on fetal weight would be produced only at 10 times the administered dose at which similarly minimal effects on maternal weight gain would occur. In the main study, the dose range was 0–120 mg/kg/day. The conclusions was reached by the study authors that developmental toxicity (reduced fetal weight) was shown in the absence of maternal toxicity; however, analysis of variance showed a significant decrease in maternal weight gain during the treatment period (Table 11 in the original report; ANOVA confirmed by me using GraphPad Prism software). Applying the benchmark dose approach to this data set yielded a BMDL of 82–87 mg/kg/day (depending on choice of model) for this parameter. The BMDL approach for mean fetal weight gives a BMDL of 28 mg/kg/day. My confidence in this comparison is reduced, however, by two observations: (1) The BMDL model fit is poor for maternal weight gain during the treatment period because the low-dose phenol group showed significantly greater weight gain than the control group. The authors of the report state that this result was due to one outlier dam, but when I excluded the weight of that dam from the analysis, there was no appreciable change in

[1] Kavlock RJ. Structure-activity relationships in the developmental toxicity of substituted phenols: in vivo effects. Teratology 1990;41:43-59.
[2] Research Triangle Institute. Teratologic evaluation of Phenol (CAS No. 108-95-2) in CD Rats. PB83-247726.

the BMDL or the model fit. (2) The report indicates that an unspecified number of animals in unspecified dose groups were without feed for an unspecified interval. The evaluation of maternal weight as an indicator of maternal toxicity under these conditions is not reliable.

2. RTI mouse developmental toxicology study[3]: In a pilot study, the phenol dose range was 0–400 mg/kg/day. Maternal weight gain during the treatment period was reduced, with a BMDL of 57 mg/kg/day. Fetal weight was decreased with a BMDL of 83–120 mg/kg/day (depending on the model). Thus, maternal weight was a more sensitive endpoint than fetal weight. In the main study, the phenol dose range was 0–280 mg/kg/day. The BMDLs for maternal weight gain during the treatment period and for absolute maternal weight gain were 127 and 25 mg/kg/day, respectively. Absolute weight gain, which excludes the gravid uterus, was a more reliable indicator of maternal toxicity in this study because the weight of the gravid uterus was significantly reduced by treatment (through an increase in resorptions and a decrease in fetal weight). The BMDLs for resorptions per litter and for fetal weight were 61 and 164 mg/kg/day, respectively. Thus, maternal body weight (excluding the gravid uterus) is considerably more sensitive to phenol effects than are developmental parameters.

3. Argus rat development toxicology study[4]: The dose range in a pilot study was 0–360 mg/kg/day. There were no significant effects of treatment on maternal weight, maternal weight gain, or fetal weight (based on ANOVA performed by me using data provided in the report). In the main study, the dose range was 0–360 mg/kg/day, with a larger number of animals per dose group than in the pilot study. Maternal weight gain during the treatment period was reduced by treatment with a BMDL of 85 mg/kg/day. Fetal weight was decreased with a BMDL of 362 mg/kg/day. Thus, maternal weight gain was considerably more sensitive to phenol treatment than was fetal weight.

4. Two generation rat reproductive study[5]: This study used phenol in drinking water at concentrations of 0–5000 ppm. There was a significant decrease in water and feed consumption in the high dose group. Male body weight was decreased at week 10 and body weight gain was decreased at week 1. BMDLs for these endpoints were 4051 and 3110 ppm, respectively. Female body weight was decreased at week 1 and 10 and body weight gain was decreased at week 1. BMDLs for these effects were 5305, 3983, and 1654 ppm, respectively. Total weight gain in the premating period was reduced for males and females with BMDLs of 2845 and 2556 ppm, respectively. The weight in high dose parental (P) females was lower in the high dose group than in the other groups, but BMDL could not be calculated because mean body weight was only shown graphically without indication of errors (SD or SEM). F1 and F2 litter weights on postnatal day 0 were decreased with BMDLs of 5119 ppm (F1) and 5014 ppm (F2). Thus, premating parental weight was considerably more sensitive to phenol effects than offspring weight on postnatal day 1. Calculating BMDLs for litter weights on postnatal days 4, 7, 14, and 21 showed increasing sensitivity with age of the offspring, with postnatal day 21 BMDLs of 1846 ppm (F1) and 1648 ppm (F2). The increased sensitivity to phenol toxicity may be associated with the likelihood of direct exposure of the offspring to treated drinking water. Water consumption of these offspring was not recorded. The percent live offspring on postnatal day 4 was decreased for P matings and F1 matings with BMDLs of 5062 and 5216 ppm, respectively. The percent live offspring from day 7 to 21 was decreased in the F1 matings with a BMDL of 5191 ppm. Thus, these parameters were less sensitive to phenol than was premating weight in the parental generation. This study included developmental landmarks in the F1 generation, which were delayed in the high dose group. Body weight at onset of the landmark was reported as well. There was a reduction in body weight at onset of

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[3] Research Triangle Institute. Teratologic evaluation of Phenol (CAS No. 108-95-2) in CD-1 mice. PB85-104461

[4] York RG. Oral (gavage) developmentaltoxicity study of phenol inrats. Final study report June 26, 1997.

[5] Ryan BM, Selby R, Gingell R, Waechter JM Jr, Butala JH, Dimond SS, Dunn BJ, House R, Morrissey R. Two-generation reproduction study and immunotoxicity screen in rats dosed with phenol via the drinking water. Int J Toxicol 2001;20:121-142.

preputial separation and at onset of vaginal patency in the high dose group; in other words, these animals weighed less at the age when the landmarks were obtained than did control animals. A comparison of weight/landmark BMDLs for males and females gave 2534/2896 and 3324/4199, respectively. Thus, body weight reduction was more sensitive than maturational landmark in both sexes. Reproductive organ weights were obtained in the parental generation. Only relative weights were presented, showing an increase in relative weight for testis and epididymis in the top dose group. The increase in relative organ weight appears proportional to the decrease in body weight, suggesting that there was no phenol effect on testis and epididymis, a conclusion supported by the normal reproductive parameters for parental males. In the F1 generation, testis and epididymis weight were decreased at the top dose, with BMDLs of 4119 and 5081 ppm, respectively. BMDLs for final body weight decrease in males was 2436 ppm. Thus, body weight was more sensitive to phenol treatment than testis or epididymis weight. Prostate weight was decreased at all phenol doses, with the high-dose group mean weight reduced by 15% compared to control. Because of the shape of the dose-response curve, BMDL calculation failed, but visual inspection suggests a BMDL less than 200 ppm for this endpoint. The same is true of uterine weight, which was also decreased at all phenol doses. The BMDL for final female body weight as 3916 ppm in the F1 generation. The effect on prostate weight was not explained by histology, which was reportedly normal. The effect on uterine weight appeared to be due, at least in part, to a higher proportion of control females being in estrus or proestrus compared to high-dose females. Males and female reproductive performance in all phenol-treated groups was normal, raising the question of whether the effects on prostate and uterine weight were biologically important. In addition, the effects on prostate weight appeared due at least in part to effects on body weight. Relative prostate weight was not significantly decreased in the highest dose group, although it was decreased in the 1000 ppm group. BMDL calculated on relative prostate weight was 2717 ppm, which was comparable to the BMDL of 2436 ppm for phenol depression of terminal body weight in F1 males.

I have reviewed other studies cited in the Hazard Identification Document dated July 2003. These studies do not report data in a manner permitting BMDL calculation.

Discussion

The US EPA Guidelines for Developmental Toxicity Risk Assessment[6] indicates the importance of considering maternal as well as developmental endpoints in developmental toxicology studies, saying "Since the final risk assessment not only takes into account the potential hazard of an agent, but also the nature of the dose-response relationship, it is important that the relationship of maternal and developmental toxicity be evaluated and described." At the time these guidelines were written, the use of a benchmark dose approach was being evaluated by the agency but had not been adopted. The agency has since suggested this approach as a possible technique for the analysis of dose-response relationships in toxicology studies, writing, "The benchmark dose (BMD) approach provides a more quantitative alternative to the first step in the dose-response assessment than the current NOAEL/LOAEL process for noncancer health effects…"[7]

Because the benchmark dose approach uses the entire dose-response curve to model effect levels, it may give a better basis for a comparison of adult toxicity and developmental/reproductive endpoints than a NOAEL/LOAEL approach, particularly when toxicity endpoints are seen only at the high dose. The appearance of adult toxicity and developmental/reproductive toxicity at the same (high) dose does not necessarily mean that the developmental/reproductive toxicity is due to the adult toxicity. In the case of phenol, however, the dose-response models developed using the benchmark dose software indicate that

[6]US Environmental Protection Agency. Guidelines for Developmental Toxicity Risk Assessment (December 5, 1991) Federal Register 56(234):63798-63826.

[7] US Environmental Protection Agency. Draft Guidance Document abstract, which appears at http://cfpub1.epa.gov/ncea/cfm/recordisplay.cfm?deid=22506. The draft guidance document itself is not citable.

effects on adult weight should be anticipated at exposure levels lower than those at which developmental or reproductive endpoints appear.[8]

In addition, the developmental endpoints identified as related to phenol treatment are endpoints (chiefly fetal weight) that would be expected to be affected secondary to maternal toxicity. None of the phenol studies shows an increase in congenital malformations, and there is no indication of impaired fertility, even at exposure levels that are clearly toxic to the adult.

In conclusion, an evaluation of dose-response curves in the phenol developmental and reproductive studies suggests that effects on development are secondary to impaired maternal health and are not due primarily to phenol exposure. Phenol has not been clearly shown to cause reproductive or developmental toxicity.

Sincerely yours,

Anthony R. Scialli, M.D.
Professor
Department of Obstetrics and Gynecology

[8] The RTI rat developmental toxicology study is a possible exception, but the maternal weight data in this study are considered unreliable due to technical problems in feed availability.

From: Mark Johnson
To: Williams, John (ECY);
Subject: Comments on Children"s Safe Products Act Proposed Rules
Date: Friday, January 07, 2011 3:14:30 PM

John Williams
Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

Dear Mr. Williams:

I am writing to comment on the draft rules for the Children's Safe Products Act – Reporting Rules, Chapter 173-334 Washington Administrative Code, as required by ESSHB 2647 from the 2008 Legislative Session.

The Washington Retail Association is very interested in continuing its involvement with this and any other CSPA activities. The safety of our member's products is of the utmost importance for not only children but for all customers.

I have met with stakeholders and discussed the draft rules with members of our association. The following are a composition of the comments I received.

Suggested additions are in blue and deletions are in red. As has been the case in other states dealing with CSP we believe it is important to establish fair and obtainable lines of responsibility for reporting requirements. These requirements need to be adaptable within existing and reasonable business practices. In particular the unique agreements and operations with regards to Private Label Retailers (PLRs) need to be acknowledged and addressed. Additionally, having uniformity among states with regards to CSP would make compliance issues for retailers easier to adhere to. A patchwork of state regulations on the same issue makes it particularly burdensome for multi-state retailers.

NEW SECTION

WAC 173-334-040 What definitions apply to terms used in this chapter? "Chemical Abstracts Service number" means the number assigned for identification of a particular chemical by the Chemical Abstracts Service, a service of the American Chemical Society that indexes and compiles abstracts of worldwide chemical literature called *Chemical Abstracts*.

"CHCC list" means the reporting list of chemicals that the department has identified as high priority chemicals of high concern for children.

"Child" means an individual under twelve.

"Department of health" means the Washington state department of health.

"Product category." For those products intended for children three years of age and under, product category means the "brick" level of the GS1 Global Product Classification (GPC) standard, which identifies products that serve a common purpose, are of a similar form and material, and share the same set of category attributes. For all other children's products, product category means the "class" level within the hierarchy of GS1 Global Product Classification (GPC) standard.

"Product component" means a uniquely identifiable piece, substrate, or coating (including ink or dye) that is intended to be included as a part of a finished children's product.

"Distributor" does not include a retailer.

"Produce" means to physically make a product.

"Producer" is a person or entity that produces a product.

"Retailer" means a person who sells, supplies, or offers for sale, directly to a consumer in the State, a regulated product not produced by that person.

NEW SECTION

WAC 173-334-100 Who is required to provide notice to the department? (1) The manufacturer of a children's product as defined in RCW 70.240.010, or a trade organization on behalf of its member manufacturers, must provide notice to the department that the manufacturer's children's product component contains a chemical on the CHCC list.

(2) The definition of manufacturer in RCW 70.240.010 includes any person or entity that produces a children's product, any importer that assumes ownership of a children's product, and any domestic distributor of a children's product. However, it is only necessary for one person or entity to provide notice with respect to a particular children's product.

~~Absent an agreement to the contrary among multiple persons or entities meeting the definition of manufacturer of a particular children's product, the following hierarchy will determine which person or entity is responsible for providing notice for the children's product:~~

~~(a) The person or entity that had the children's product designed or manufactured, unless it has no presence in the United States.~~

~~(b) The person or entity that marketed the children's product under its name or trademark, unless it has no presence in the United States.~~

~~(c) The first person or entity, whether an importer or a distributor, that owned the children's product in the United States.~~

~~In no event may entities meeting the definition of manufacturer with respect to a particular children's product delegate notice responsibility to a person or entity with no presence in the United States.~~

(3) An importer shall not be held responsible for the obligations of a manufacturer if the importer (a) obtained written assurances from the producer that the producer would comply with the notification requirements herein, (b) reasonably relied on those assurances, (c) promptly notified the State of producer's noncompliance after becoming aware of producer's noncompliance, and (d) reasonably cooperates with the State, including stopping sale of the product, as applicable.

The following comments were submitted by the Association of Washington Business. WRA, a member of AWB, agrees and supports the comments made below:

1) The threshold of 40 ppm (.001%, or .00001) is far too low, and beyond the ability of modern testing equipment to accurately measure at that extremely low level. Instead, AWB supports adopting a standard consistent with the European Union of 1,000 ppm (.1%) which has been determined worldwide to be more than adequately protective of human health.

2) The reporting requirements should be limited to those chemicals that a manufacturer intentionally adds to a product. A manufacturer should not be required to test for chemicals that are not part of the product manufacturing or design.

3) The list of chemicals manufacturers are required to report needs trimming. As the Department of Health and the University of Washington reported in July of this year, 27 of the chemicals on Ecology's list are not likely to be intentionally added to products. Those 27 chemicals should therefore be removed from the reporting requirements.

4) The reporting rule should be limited to product components that a child is likely to contact. Internal parts and parts that are inaccessible and not likely to come into contact with children through reasonable and foreseeable use should be exempted from the reporting obligations of the rule.

In addition, food and food packaging should be specifically exempted from the rule, as those products are regulated by the federal Food and Drug Administration.

My final comment is in regards to the Small Business Economic Impact Statement submitted in October 2010. WRA has many small members within Washington state that are likely to be negatively impacted by these new regulations in the form of compliance costs and higher prices. This is disturbing in the light of our current deep recession all businesses are struggling to survive. In particular I find the statement in

the executive summary considerably “off base” and inacurrate, quote: “ Ecology estimated that the costs and payments created by the proposed rule will likely reduce employment in the state by up to 0.5 positions over 20 years, across the state economy, for all sizes of businesses. This accounts for the flow of compliance expenditures through the economy as earnings, wages, and further spending.”

Thank you for the opportunity to comment on the proposed rules.

If you have any questions regarding the comments or need further clarification, please do not hesitate to contact me directly.

Sincerely,

Mark Johnson

Vice President of Government Affairs
Washington Retail Association

PO Box 2227
Olympia, WA 98507-2227
USA

Office: 360-943-9198 ext 15
cell: 360-704-0048
FAX: 360-943-1032

From: Struyk, William [JJCUS]
To: Williams, John (ECY);
cc: Terwilleger, Karen (ECY); Sturdevant, Ted (ECY); Justin, Jim (GOV); Phillips, Keith (GOV); Burrell, Kari (GOV); Kraege, Carol P. (ECY); Wille, Kathleen K. [CPCUS]; Turek, Elizabeth [CPCUS]; Swei, Homer [CPCUS]; Struyk, William [JJCUS]; sbuckner@frontier.com;
Subject: Comments on Proposed Children"s Safe Product Act Rule
Date: Friday, December 03, 2010 12:17:09 PM
Attachments: CSPA Rule Comments 12 2 10.doc

John,

In follow up discussions to the original Johnson & Johnson comment letter on the draft rules you indicated that we may have mischaracteri ed the Department's position on its support of de minimis trigger value of 1000 ppm. Since this was not our intent we are asking you and those copied on this email to disregard the original letter and use the attached letter as our final comments on the draft rule.

I would personally apologi e for any mischaracteri ation but would emphasi e our strong support of a trigger threshold for intentionally added ingredients of 1000 ppm which is a widely accepted trigger value used by the European Union and California's Prop 65.

Please do not hesitate to contact me with any uestions or concerns.

Bill Struyk

425-235-5186

<<CSPA Rule Comments 12 2 10.doc>>

 238

Johnson & Johnson

December 2, 2010

John R. Williams
Washington State Department of Ecology
W2R HQ
PO Box 47775
Olympia, WA 98540-7775

Re: Comments on Draft Reporting Rule for Children's Safe Products Act of 2008

Dear Mr. Williams,

Johnson & Johnson appreciates the opportunity to comment on the draft rules on the Children's Safe Products Act. As you know, the Department of Ecology invited Johnson & Johnson to participate in the pilot rule process and Johnson & Johnson did participate to help ensure the resulting rules would achieve the statutory direction to focus on high priority chemicals selected "…on the basis of credible scientific evidence as known to do one or more of the following…".[1.]

The Governor's veto message directs the Department to "…rely on safety testing conducted in the European Union and California, to the extent they provide a reasonable assurance of safety, in order to help establish a decree of consistency for the industry."[2.]

***De minimis* quantities:**

The Department's "Phase 3 Report" states, "Concentration of chemicals of concern present at 0.1% in product components (1000 ppm) is a ***commonly accepted value, used by jurisdictions such as the European Union, to indicate that a chemical is intentionally added to product".*** Both the European Union GHS Classification and Labeling program and California Proposition 65 have adopted a 1000 ppm threshold unless a different level is identified based on a health risk assessment. Instead, Ecology chose to bracket reporting ranges as follows:

(i) Equal to or more than 40 ppm (0.004%) but less than 200 ppm (0.02%);
(ii) Equal to or more than 200 ppm (0.02%) but less than 1000 ppm (0.1%);
(iii) Equal to or more than 1000 ppm (0.1%) but less than 10,000 ppm (1.0%);
(iv) Equal to or more than 10,000 ppm (1.0%) but less than 100,000 ppm (10%); or
(v) Equal to or more than 100,000 ppm (10%)

There should be no reporting requirement for incidental traces that occur at insignificant levels. If there must be a threshold to determine when the level of an incidental trace is low enough to be insignificant, then the threshold for incidental traces should ideally be 1000 ppm; not 40 ppm.

 238

 239

Parabens:

Butyl, ethyl, methyl, and propyl paraben should be excluded from the list because the only hazard information that supports their listing is from the EU Endocrine Disruption information. As the Department is aware, the EU Endocrine Disruption information had no deliberative scientific review or decision-making by EU authorities nor any input from stakeholders. The EU's Science Advisors determined "that there are "important shortcomings in the present approach".

The Department should look to results from validated protocols from the EPA's Endocrine Disruptor Screening Program (EDSP) Tier 2 testing. The EPA has been developing protocols for the EDSP for 12 years, with a Tier 1 testing program designed to identify chemicals with the potential to interact with the endocrine system and for those chemicals found to have that potential, there is Tier 2 testing which is designed to determine the dose-response relationships for adverse effects.

Current regulations require that parabens be listed on the product label; therefore, reporting is redundant and does not provide any additional information on their use. The FDA has this information as part of the Voluntary Cosmetics Reporting Program, and summaries on the use of parabens can be obtained from the US FDA. Propylparaben, butylparaben, methylparaben, and ethylparaben should be removed from the CHCC list. Alternatively, we propose exempting any chemical on the CHCC list from the reporting requirement if it is listed on the product packaging.

SUMMARY

The safety and well-being of babies and all of our consumers is of the utmost importance to us. To ensure that we are offering safe products, we do the following:

- We specifically formulate our baby products to meet their unique cleansing needs.
- The best and most complete science substantiates the safety of our products in use, and we are continuously reviewing and assessing the science.
- Our products are comprehensively evaluated for safety, prior to introducing a product into the marketplace.
- Healthcare professionals review our safety data, are familiar with all of the steps we take, and have confidence in our products.
- We have a well developed system to track consumer feedback and evaluate safety data, and we are continually reviewing new scientific studies, regulations and stakeholder input. If credible, new evidence raises concerns about an ingredient—even if it meets government regulatory requirements—we will reduce or eliminate it, as needed, to ensure the highest levels of safety. In addition, we may also reformulate products for a number of other reasons including: new scientific information, better performance, changing consumer preferences and stakeholder input, and to reduce environmental impact.
- We are researching the next generation of baby product ingredients. Of course, if we replace an ingredient, it must also meet our rigorous standards and be proven and tested to be safe before we use it. We are committed to continuously evolving our products to support the changing nature of personal care. In doing so, it is our goal – and commitment – to set high standards for the industry.

The safety of our products is supported by clinical testing, independent review by leading healthcare experts, international regulatory agencies, and many years of real-world use by babies and other consumers. Federal

 239

240

regulatory agencies in the U.S. and Europe have reviewed the science and concluded that the trace levels of certain compounds are present in such extremely small amounts they are completely safe.

As is required under the Federal Food, Drug, and Cosmetic Act, the substantiation of safety is the responsibility of the manufacturer. We have hundreds of scientists and experts in Research and Development; it is redundant and a waste of the state's limited resources to develop a staff of experts to develop a credible, scientifically sound program to re-evaluate the ingredients used in cosmetic products. As, previously stated, the use of parabens can easily be obtained from Food and Drug Administration's Voluntary Cosmetic Reporting Program.

Sincerely,

Kathleen K Wille, PhD
Sr. Director, Product Stewardship
Johnson & Johnson Consumer & Personal Products Company Worldwide,
Division of Johnson & Johnson Consumer Companies, Inc.
199 Grandview Road
Skillman, New Jersey 08558

Beth Turek
Sr. Director, Regulatory Affairs
Johnson & Johnson Consumer & Personal Products Company Worldwide,
Division of Johnson & Johnson Consumer Companies, Inc.
199 Grandview Road
Skillman, New Jersey 08558

Homer Swei, PhD
Associate Director, Product Stewardship
Johnson & Johnson Consumer & Personal Products Company Worldwide,
Division of Johnson & Johnson Consumer Companies, Inc.
199 Grandview Road
Skillman, New Jersey 08558

William Struyk
Sr. Director State Government Affairs
Johnson & Johnson Services Inc.
4707 Smithers Ave S
Renton, WA 98055

1. R.C.W. 70.240.010 (6)
2. Governor's Partial Veto message dated April 1, 2008.

Cc: Carol Kraege
Karen Terwilleger
Ted Sturdavant
Jim Justin
Keith Phillips
Kari Burrell

240

From: Tom Lewandowski
To: Williams, John (ECY);
Subject: Comments on proposed CSPA regulations
Date: Friday, December 31, 2010 4:22:57 PM
Attachments: Lewandowski CSPA comments.pdf

Dear Mr. Williams,

Attached are my comments on the proposed regulations for the Children's Safe Product Act Reporting Rule. Thank you for the opportunity to participate in this important rule making.

Sincerely,

Thomas A. Lewandowski, Ph.D., DABT, ERT
Toxicologist
Gradient
600 Stewart Street, Suite 803
Seattle WA 98101

Gradient

December 31, 2010

John R. Williams
Department of Ecology
W2R HQ
PO Box 47775
Olympia WA 98540-7775

RE: Children's Safe Product Act Reporting Rule

Dear Mr. Williams:

Attached please find official comments related to the proposed Children's Safe Product Act Reporting Rule. These comments supplement oral testimony I provided at the December 9, 2010 public meeting in Lacey, Washington.

Sincerely,

Thomas A. Lewandowski, Ph.D., DABT, ERT
Toxicologist
Gradient
600 Stewart Street, Suite 803
Seattle WA 98101
206-267-2924
206-267-2921 (fax)
tlewandowski@gradientcorp.com

G:\Projects\Green Chemistry\WA CSPA comments.docx

Written Testimony Concerning Proposed WAC 173-334
Submitted by Thomas Lewandowski, Ph.D., DABT, ERT
Gradient
Seattle, WA
December 31, 2010

My name is Thomas A. Lewandowski. I am a Principal Scientist at Gradient, a health risk consulting company with offices in Seattle Washington and Cambridge Massachusetts. My practice areas include consumer product safety, green chemistry, and reproductive and developmental toxicology. I am board certified in toxicology by the American Board of Toxicology and I am a Registered Toxicologist with the European Society of Toxicology. I am an Adjunct Associate Professor of Environmental Health at Brooklyn College in Brooklyn, NY and an Affiliate Associate Professor of Environmental Health at the University of Washington in Seattle.

I would like to commend the Washington Department of Ecology for initiating this timely effort to address the important issue of chemical risks associated with children's products. Due to a number of well publicized incidents, the issue is one of great concern to the public. As a Washington resident, I am proud to see my State assume a leading role in addressing this important issue. In that vein, I offer the following comments and suggestions on the draft regulations.

WAC 173-334-010. I appreciate the statement included in the introduction indicating that "the presence of a CHCC [chemical of high concern to children] does not establish that the product is harmful to human health" but the regulations need to do more to better reflect this statement. As explicitly stated in the introduction, the law will provide the Department of Ecology with data on the chemicals present in children's products sold in Washington State. However, the law will also result in dissemination of the information Ecology collects to the public at large because any information that is not claimed as confidential business information will be available by request under the Washington Public Records Act. Based on comments given by individuals at the December 9th public meeting, is seems highly likely that information submitted by manufacturers to Ecology will be used by 3rd parties to designate products containing listed chemicals as "toxic" or "dangerous" without any regard to the potential for exposure. Yet health risk is a function of not only inherent toxicity but exposure as well. Ecology should adopt a proactive approach for sharing the acquired information with the public in a way that educates consumers about the potential risks of products. For example, the Agency should consider making the information available *via* an Ecology-maintained web-site rather than passively allowing this task to be assumed by other groups.

WAC 173-334-070 and WAC 173-334-080. The regulations allow for public petitions for listing/delisting of chemicals from the list and require that the petitioner provide "Credible peer-reviewed scientific information documenting why the chemical meets the criteria required for inclusion on the list." What is the standard for credible and peer-reviewed information? Does this mean publication in a scientific journal? Unfortunately not all journals are of high quality or undergo thorough peer review. Is one study of adverse health effects sufficient? What if there is one positive study but a number of negative studies? Some weight-of-evidence analysis will need to be used in which the quality of specific information and the totality of the available information is assessed. It would be helpful if Ecology stated that this type of approach will be used in this section of the regulation.

WAC 173-334-090. Regarding the threshold concentrations for reporting, a number of individuals at the December 9th public meeting stated that reporting should be based on chemical detection and should not involve a reporting threshold. Adopting such an approach would create several problems. First, detection of chemicals in complex organic matrices (*e.g.*, plastics, rubber, other polymers) may

be quite challenging compared to detecting those chemicals in water or soil. There will be a fairly substantial likelihood of false positive and false negative results near the detection limit. Detection limits will also change over time, and reporting may become detection limit driven rather than responding to actual health risks. Second, a "detectable" threshold would encourage disreputable parties to use the least sensitive method available to analyze their product. This in turn would force Ecology into the role of specifying particular test methods, which, given the large number and complexity of matrices involved, would likely exceed the Agency's resources. Finally, a number of those testifying at the public meeting noted that some chemicals are very toxic even in extremely small amounts. While this is true, most chemicals are NOT toxic in extremely small amounts (*i.e.*, µg/kg or ng/kg concentrations). Thus, the desire to have "detectable" as the reporting threshold for all chemicals is illogical and unnecessarily burdensome. The current regulations specify a lower reporting threshold of 40 ppm. Given that the products being addressed (*e.g.*, toys, car seats, blankets) are not intended or designed to transfer their chemical constituents to their users, a reporting threshold of 40 ppm in the product is sufficient. For a particular chemical that is found to be exceptionally toxic and is found in children's products, Ecology has the ability to develop a chemical-specific reporting requirement.

WAC 173-334-090. In terms of reporting, the regulation (and underlying CSP Act) allows the regulated community to include "[a]ny other information the manufacturer deems relevant to the appropriate use of the product." This would appear to allow for manufacturers to include information concerning why the presence of a chemical in a product may not pose a risk (*i.e.*, addressing the exposure component of risk rather than only the hazard component). This could potentially be used to address the concerns raised above under WAC 173-334-010. For example, Ecology could create a series of codes, similar to the risk phrases used in the EU, which would allow the manufacturer to provide additional information about exposure potential (*e.g.*, E1 - chemical is present on product surface or surface coating, E2 – chemical is part of an insoluble matrix, E3 – component containing chemical is too large to fit into a child's mouth, E4 – saline leach testing indicates no detectable migration of chemical, *etc.*). Codes would simplify the information and circumvent lengthy text explanations. Ecology should also make specific provisions for allowing manufacturers the *option* of submitting data on product extraction testing (*e.g.*, *via* ASTM F-963 which simulates the extraction ability of human saliva) in addition to total content results. This would again provide Ecology and the public with more useful data on potential health risks.

WAC 173-334-140. The list of chemicals should include some descriptive statement as to why a chemical was chosen (*e.g.*, carcinogenicity, developmental toxicity, bioaccumulative potential). Lists such as these are often used by 3rd parties in conducting health screening evaluations and it would be helpful to know the basis for listing. This type of approach is used by the State of California in the Proposition 65 program.

WAC 173-334-120. Tier 4 covers products where the CHCC is part of the product internal structure and is not intended for direct contact with the skin or mouth. Is it Ecology's position that manufacturers do not need to consider consumers behaving in unintended ways? Tier 4 products have no specified reporting timeline and are to be decided by Ecology on a case-by-case basis. How are manufacturers to know whether Ecology is considering their product? What standard will be used to make this determination? Reporting requirements (and penalties for not reporting) for Tier 4 manufacturers should be dated from the time Ecology makes the determination that a report is necessary.

From: Allen Blakey
To: Williams, John (ECY);
cc: Allen Blakey;
Subject: Comments on proposed WAC 173-334 - Vinyl Institute
Date: Thursday, December 30, 2010 9:58:07 AM
Attachments: CSPA Draft Regs-Vinyl Inst 2010-12-30.pdf
CSPA Draft Regs-Vinyl Inst p2 2010-12-30.pdf

Dear Mr. Williams,

Please accept these comments on the Department of Ecology's proposed regulations to implement the Children's Safe Products Act. There are two separate scans, one for each page of our comments.

The Vinyl Institute appreciates this opportunity to comment, and we are available to answer questions or provide additional information. You can reach me at 571-970-3283 or at ablakey@vinylinfo.org.

Sincerely,

Allen Blakey

Allen Blakey
Vice President of Industry and Government Affairs
The Vinyl Institute
1737 King Street Suite 390
Alexandria, VA 22314
Direct: 571.970.3283
Mobile: 703.622.3886
Fax: 571.970.3271
Email: ablakey@vinylinfo.org
http://www.vinylinfo.org
http://www.vinylindesign.com

The Vinyl Institute

December 30, 2010

SENT VIA ELECTRONIC MAIL

Mr. John R. Williams
Washington State Department of Ecology
W2R HQ
P.O. Box 47775
Olympia, WA 98540-7775
jowi461@ecy.wa.gov

RE: Comments on Proposed WAC 173-334

Dear Mr. Williams,

The Vinyl Institute (VI) appreciates the opportunity to comment on the Department of Ecology's (DOE) WAC 173-334, proposed regulations to implement the Children's Safe Products Act.[1]

VI supports the comments filed by the American Chemistry Council (ACC). In addition, we respectfully wish to comment on particular parts of the proposed regulations.

We strongly support the protection of children and other consumers from adverse impacts related to the use of products and materials. We also support the creation of a process by which chemicals of high concern to children (CHCC) are identified and prioritized.

We commend DOE for acknowledging the importance of risk and exposure when identifying and prioritizing CHCCs. We agree with the statement in the introduction to the proposed rule that "the presence of a CHCC does not establish that the product is harmful to human health." This comports with the policies of other health and safety agencies such as the U.S. Environmental Protection Agency and Centers for Disease Control.

Chemicals that must be carefully managed are often used in the production of important consumer products which, themselves, pose little or no exposure risks. As examples, these chemicals may be raw materials that are converted into innocuous finished components, process materials that are used up in the manufacturing process, or additives that are chemically or mechanically held tightly in the product.

---

[1] The Vinyl Institute is the national trade association for U.S. manufacturers of vinyl resin, the material of choice in myriad toy, childcare, building and construction, medical, packaging, and other applications.

1737 King Street, Suite 390, Alexandria, VA 22314 tel 571.970.3283

It is not clear how the proposed list of CHCCs was developed. A transparent, scientifically based process needs to be formally established by which use and exposure criteria are given substantial consideration in identifying and listing CHCCs. We urge DOE to revise and clarify the proposed rule so as to:

- provide a clear, consistent, risk-based methodology for identifying chemicals that are toxic, persistent or bioaccumulative, and have the potential for harmful exposure;
- set appropriate threshold reporting levels for the prioritized chemicals, and
- require reporting and other actions under this rule only for those chemicals present at or above the threshold levels.

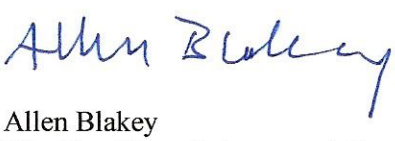
The proposed rule sets a *de minimis* concentration level for reporting at 40 ppm (0.004%). VI strongly supports a *de minimis* provision, but we believe that this proposed level should be consistent with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) that has been adopted by a number of U.S. agencies. We agree with ACC that a more effective, realistic and consistent reporting threshold is 1,000 ppm (0.1%). While state or federal statutes may set lower permissible limits for some individual substances (e.g., 40 ppm for cadmium and 90 ppm for lead), a higher across-the-board reporting threshold is appropriate for such a broad regulation. As noted above, reporting and other provisions of the rule should apply only to chemicals present above the *de minimis* level. Manufacturers could be required to maintain records supporting the *de minimis* exemption of any chemicals otherwise regulated under this rule.

We also support the proposal to establish a process for revising the list of CHCCs and delisting a substance.

VI believes that DOE needs to consider carefully how this rule is implemented and communicated so that consumers and businesses in Washington understand the differences among a) the use of a chemical to make a product, b) the presence of a chemical in a product and c) the risk of exposure to a chemical in a product. Otherwise, this rule could have potentially significant consequences on consumers' attitudes toward products that have a history of safe, effective use in the State. The rule should be implemented in a way that makes its objectives and procedures clear and that minimizes the likelihood of unintended consequences.

We appreciate this opportunity to comment and are available to answer questions or provide additional information. You can reach me at 571-970-3283 or at ablakey@vinylinfo.org.

Sincerely,



Allen Blakey
Vice President, Industry and Govt. Affairs
The Vinyl Institute

1737 King Street, Suite 390, Alexandria, VA 22314 tel 571.970.3283

From: Michelle Mikkelsen
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 2:11:19 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Michelle Mikkelsen
2112 179th CT NE
2112 179th Ct NE
Redmond, WA 98052

From: Bart Queary
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 02, 2010 11:53:51 AM

Dept. of Ecolgy

Dear John R. Williams,

As concerned consumers, we appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to us and we hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Consumers, especially young parents buying for their children, deserve full information on all the contents of everything they give to their children. Let's not let the manufacturers decide what parents should know.

Thank you for your consideration,

Bart & Peggy Queary
9613 SW 268th St.
Vashon, WA 98070

206-463-1977

Bart Queary
9613 SW 268th St.

250

Vashon, WA 98070

250

From: lAURIE HOGGARD
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 02, 2010 11:13:58 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

lAURIE HOGGARD
3116 N 27TH
Tacoma, WA 98407

From: Liz Banse
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, November 09, 2010 9:11:23 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Liz Banse
6540 49th Ave NE
Seattle, WA 98115

From: Tamara Adams
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 2:29:33 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Tamara Adams
17725 Hall Road Apt 109
Bothell, WA 98011

From: Ana Rivero
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 27, 2010 1:52:42 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Ana Rivero
5809 149th Ave SE
Bellevue, WA 98006

From: thom laz
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Saturday, January 01, 2011 10:39:13 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

thom laz
2321 fairveiw E#5
Seattle, WA 98102

From: Laurie Solomon
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Friday, December 31, 2010 5:30:23 AM

Dept. of Ecolgy

Mr. John Williams,

Please consider this to be my public comment on the Safe Product Act Reporting Rule. The health of the next generation is very important to me and I urge you to ensure that the Department of Ecology adopts a strong rule that:

* Requires companies to report when and where they are using a toxic chemical so that the Department of Ecology can prioritize taking action on the worst problems first.

* Prioritizes identifying and reporting of chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

*Requires companies to report meaningful information on how much a toxic chemical is being used in a product so that the Department of Ecology can fix the worst problems first.

* Requires manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels. It is the right of the public to know what is in the products we are buying

* Ensures wide and easy access by the public to information on the chemicals used in specific products. Again, it is the right of the American public to know what is in the products we are buying.

Just as the consumers in European countries have demanded this information be made available to the public, and that labeling laws be enforced by the governing agencies responsible for public health, so should we be demanding that information on toxic chemicals be made available to us.

Thank you for your consideration of this comment,

Laurie Solomon
POB 1342

 257

Battle Ground, WA 98604

 257

From: Lou & Joan Truskoff
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 28, 2010 4:39:44 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Lou & Joan Truskoff
118 N. 58th St.
Seattle, WA 98103

From: Angela Kelly
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 28, 2010 11:40:43 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Angela Kelly
1817 Adams St SE
Olympia, WA 98501

From: Corey Weathers
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 28, 2010 10:44:58 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Corey Weathers
16537 NE 117th Way
Redmond, WA 98052

From: karen price
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 27, 2010 6:25:56 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

karen price
11626 7th ave sw
burien, WA 98146

From: Rick Romito
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Sunday, December 26, 2010 9:27:25 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Rick Romito
4534 Fir Tree Way
Bellingham, WA 98229

From: Cal Roberts
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Friday, December 24, 2010 8:48:18 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Cal Roberts
504 NE 139th Ave
Vancouver, WA 98684

From: Patricia Brady
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Friday, December 24, 2010 2:57:48 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Patricia Brady
9547 Berkshire Ct SE
Lacey, WA 98513-4844

From: Suzanne Hostetter
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Friday, December 24, 2010 9:08:36 AM

Dept. of Ecolgy

Dear John R. Williams,

Thank you for accepting comments on this important piece of legislation. The Children's Safe Product Act will go a long way to move us forward in protecting the health of future generations and strongly urge the Dept. of Ecology to adoopt it. We need to know what chemicals and compounds are in the products we use and/or to which we are exposed. Please ensure that we have a strong act that:

* Requires companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritizes chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Requires companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Requires manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensures wide and easy access by the public to information on the chemicals used in specific products.

Respectfully submitted,

Suzanne Hostetter
Rochester, WA

Suzanne Hostetter
P.O. Box 717
16648 Littlerock Rd. SW
Rochester, WA 98579

From: Jami CUPICCIA
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 7:49:48 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Jami CUPICCIA
0
58 TH ST CT NW
GIG HARBOR, WA 98335

From: Deborah Martin
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 5:25:32 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Deborah Martin
6407 Dow ln
Anacortes, WA 98221

From: Janna Rolland
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 4:23:32 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Janna Rolland
6227 34th Ave NE
Seattle, WA 98115

From: Reingard Rieger
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 3:07:42 PM

Dept. of Ecolgy

Dear John R. Williams,

I remember well when I sent a baby toy to my nephew who lived in Europe about 10 years ago. His parents -- and I -- were shocked when we found out that that toy, quite common and popular in the US, contained a toxic substance and was therefore illegal where they lived.

Sadly, in this country that very same toy is still for sale because we still don't have strict rules and regulations that protect our children here.

As the Dept. of Ecology is considering the Children's Safe Product Act, I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, PVC, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

* Require companies to report meaningful information on how much a toxic chemical is being used in a product so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Reingard Rieger
8804 Ashworth Ave N

 270

Seattle, WA 98103

 270

From: Lia Slemons
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 1:44:08 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned citizen considering starting my own family soon, I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. To proactively protect the health of the most susceptible to toxics (often children) I urge Ecology to adopt a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the most widespread problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

* Require companies to report meaningful information on how much a toxic chemical is used in a product so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products. This information is something I find difficult to acquire for many products now, and I would like to see the chemicals included in products just as consumer-accessible as the ingredients label on foods.

Thank you for your consideration,

Lia Slemons
4512 Sunnyside Ave N
Seattle, WA 98103

From: alan lott
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 10:47:27 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

alan lott
612 N 61st
seattle, WA 98103

From: Heather Rosewarne
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 10:44:54 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

AS A PARENT IT IS EXTREMELY FRUSTRATING KNOWING THAT SO MANY HARMFUL PRODUCTS ARE WIDELY AVAILABLE TO OUR CHILDREN, AND IN MANY MAINSTREAM TOYS AND CLOTHING ARTICLES!

AS A NURSE I AM DEEPLY CONCERNED ABOUT THE PUBLIC HEALTH IMPLICATIONS OF TOXIC CHEMICAL EXPOSURE FOR CHILDREN.

Thank you for your consideration,
Heather Rosewarne

Heather Rosewarne
3618 35th Ave S

 274

Seattle, WA 98144

 274

From: Lillian Kuehl
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 10:27:21 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The suggestions below will not only provide regulatory incentive for manufacturers to decrease use of toxic substances in toys and other goods, but the warnings to consumers will also provide companies with economic incentives--fewer toxic ingredients means less consumer hesitation to purchase a product.

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Lillian Kuehl
1110 E Quilcene Rd
Quilcene, WA 98376

From: Leigh Bangs
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 9:40:21 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Leigh Bangs
4314 193rd Ave Se
Issaquah, WA 98027

From: Deborah Petersen
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 8:35:05 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Deborah Petersen
2532 Island Dr NW
olympia, WA 98502

From: Bryony Angell
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Thursday, December 23, 2010 8:22:19 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer and a new parent, I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Bryony Angell
1718 NE 124th St
Seattle, WA 98125

From: Laurie Thompson
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 9:50:39 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Laurie Thompson
536 129th Ave SE
Bellevue, WA 98005

From: Sam Garst
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 9:19:47 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Sam Garst
6015 Marantha Lane SW
Olympia, WA 98512-2000

From: Helga Jaques
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 9:01:16 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Helga Jaques
13114, 158th Ave. SE
Renton, WA 98059

From: Joellen Wilhelm
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 8:59:28 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Joellen Wilhelm
623 Central St SE
623 Central St SE
Olympia, WA 98501

From: Monica Villines
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 5:23:59 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Monica Villines
4930 Shellridge Rd NW
Olympia, WA 98502

From: Seth Rolland
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 3:25:58 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Seth Rolland
1039 Jackson Street
1039 Jackson Street
Port Townsend, WA 98368

From: Gretchen Cappio
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 2:39:52 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Gretchen Cappio
444 Smith St
Seattle, WA 98109

From: Loretta Jancoski
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 2:08:32 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Loretta Jancoski
14948 256th Ave. S.E.
issaquah, WA 98027

From: Kay Mullen
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 2:00:02 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Kay Mullen
2801 N. Narrow Dr. K-2
TACOMA, WA 98407

From: Colleen Hinton
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 1:51:37 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Colleen Hinton
16763 Maplewild Ave SW
Burien, WA 98166

From: Elizabeth Zimmerly
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 1:43:01 PM

Dept. of Ecolgy

Dear John R. Williams,

As a parent of a young child, I take the issue of protecting children from toxic chemicals very seriously. I make every effort to choose toys, shampoo, and other products for my child that will not harm him. It is impossible to make good choices, however, without sufficient information.

I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Elizabeth C. Zimmerly

Elizabeth Zimmerly
10033 63rd Ave. S.
-
Seattle, WA 98178

290
290
290

From: brooks anderson
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 1:40:04 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

brooks anderson
905 Wilson Ave
na
Bellingham, WA 98225

From: Dorothy Guth
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 12:05:58 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer and a new parent I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health my son and of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Dorothy Guth
716 2nd Street
Kirkland, WA 98033

From: mieko krell
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 9:41:22 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

mieko krell
547 NE 127th St.
Seattle, WA 98125

From: Patricia Hamann
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 8:50:01 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Patricia Hamann
23810 se 28th st
sammamish, WA 98075

From: Lorena Havens
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 22, 2010 8:47:55 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Lorena Havens
PO Box 179
Acme, WA 98220

From: Bob Aegerter
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 9:21:03 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Bob Aegerter
78 North Point Drive
Bellingham, WA 98229-7931

From: Boni Biery
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 4:43:04 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Boni Biery
903 N 188th St
Shoreline, WA 98133

From: Beverly Doty
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 3:32:00 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,
Beverly Doty, parent, grandparent,, great grandparent

Beverly Doty
720 NW 9th St
Vancouver, WA 98665-7536

From: Galen Davis
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 2:31:47 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Galen Davis
9114 8th Ave NE
Seattle, WA 98115

From: Dan Morris
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 2:11:31 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Dan Morris
8340 24th Ave NW
Seattle, WA 98117

From: Earlene Benefield
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 1:41:20 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Earlene Benefield
11042 108th Plqce NE
Kirkland, WA 98033

From: Samantha Guse
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 12:14:24 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer and mother of two I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

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Thank you for your consideration,

Samantha Guse
1108 NE 126th St. Loop
.
Vancouver, WA 98685

From: Claire Mikalson
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 11:48:13 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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Thank you for your consideration,

Claire Mikalson
East 302 Washington St
POBOX 135
Farmington, WA 99128

From: Yvonne Bergholm
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 11:05:17 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Yvonne Bergholm
24206 SE 38th PL
Issaquah, WA 98029

From: Jamie Coates-Robertson
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 9:38:53 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Jamie Coates-Robertson
8321 172nd Ave NE
Redmond, WA 98052

From: Trudy Antolin
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 6:50:31 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Trudy Antolin
6215 43rd Ave. NE
Seattle, WA 98115

From: Michelle Erwin
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Tuesday, December 21, 2010 12:53:00 AM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Michelle Erwin
824 234th pl se
.
Bothell, WA 98021

From: Brian Haberly
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 11:06:42 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Brian Haberly
4603 191st Place NE
Sammamish, WA 98074

From: Annapoorne Colangelo
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 10:41:50 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Annapoorne Colangelo
7651 Scatchet Head Road
Clinton, WA 98236

From: Joe Ginsburg
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 10:07:33 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Joe Ginsburg
12210 Densmore Ave. N.
Seattle, WA 98133-7729

From: Robert Moore
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 9:47:50 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Robert Moore
14727 39th Ave NE
Lake Forest Park, WA 98155

From: Bill Bryant
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 9:24:04 PM

Dept. of Ecolgy

Dear Mr. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Bill Bryant
7724 18th Ave. NW
Seattle, WA 98117

From: Cindy Callahan
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 9:16:31 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Cindy Callahan
PO Box 363
Hobart, WA 98025

From: Mare Wahosi
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 8:38:32 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Mare Wahosi
840 Retsil Ave E
Port Orchard, WA 98366

From: Valerie Sammons
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 8:21:13 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Valerie Sammons
6511 23rd Ave. NW
Seattle, WA 98117

From: Cherie Holman
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 7:30:04 PM

Dept. of Ecolgy

Dear John R. Williams,

I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

Require companies to report when and where they are using a toxic chemical.

Ensure wide and easy access by the public to information on the chemicals used in specific products.

Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

Thank you for your consideration,

Cherie Holman
4214-A Evanston Avenue N
Seattle, WA 98103

From: Jared Mitts
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 6:35:19 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Jared Mitts
6017 190th St SW
Lynnwood, WA 98036

From: Debbie Carlsen
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 6:19:13 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Debbie Carlsen
130 NE 95th Street
Seattle, WA 98115

From: Ingrid Elliott
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 4:54:47 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Ingrid Elliott
617 W. Howe St.
Seattle, WA 98119

From: Christy Cornelsen
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 4:25:12 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Christy Cornelsen
735 W. 1st St. #17
Cheney, WA 99004

From: Johari Vos
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 3:52:50 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Johari Vos
6310 19th Avenue NE
Seattle, WA 98115

From: Thom Peters
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 3:46:52 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Thom Peters
7725 Riverview Road
Snohomish, WA 98290-5884

From: Sarah Foley
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 3:03:23 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

* Prioritize chemicals that we know are harmful to children, including endocrine disrupting chemicals like parabens and phthalates, chemicals with neurotoxic effects like lead, and chemicals that harm children's development like mercury, fluoride, and bisphenol A.

Require companies to report meaningful information on how much a toxic chemical is being used in a produdct so that Ecology can fix the worst problems first.

* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Sarah Foley
7336 6th ave #14
Tacoma, WA 98406

From: Kerry Logan
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 2:57:34 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Kerry Logan
3091 Stemilt Creek Rd.
Wenatchee, WA 98801

From: Mickie Meyer
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 2:57:31 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Require manufacturers to report even low levels of harmful chemicals in their products because scientific studies show chemicals can harm children at very low levels.

* Ensure wide and easy access by the public to information on the chemicals used in specific products.

I feel very strongly about this particular issue. Consumers aren't readily given the information they need to make an informed purchasing decision. By requiring companies' full disclosure they are being held accountable and I as a consumer can rest assured that what I'm buying is safe for my children and grandchildren.

Thank you for your consideration,

Sincerely,
Mickie Meyer

Mickie Meyer

 326

15917 NE 109th Way
Redmond, WA 98052-1603

 326

From: Bruce Pringle
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 2:47:49 PM

Dept. of Ecolgy

Dear John R. Williams,

I would like to comment on the reporting rule of the Children's Safe Product Act.

The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

* Require companies to report when and where they are using a toxic chemical so that Ecology can prioritize taking action on the worst problems first.

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you,

Bruce Pringle
17037 12th PL SW
Normandy Park, WA 98166-3405

From: JAMES HARRIS
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 2:47:16 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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Thank you for your consideration,

JAMES HARRIS
11719 SE 58TH ST
BELLEVUE, WA 98006

From: Darlene St. Martin
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 2:45:34 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Darlene St. Martin
506 N Laventure Road
Mount Vernon, WA 98273

From: Scott Ellis
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 2:41:21 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Scott Ellis
14410 31st dr sd
Mill Creek, WV 98012

From: Beth Burrows
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 2:21:05 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Beth Burrows
20319-92nd Ave. West
Edmonds, WA 98020

From: Suzanne Hamer
To: Williams, John (ECY);
Subject: Comments on the Children"s Safe Product Act Reporting Rule
Date: Monday, December 20, 2010 2:13:17 PM

Dept. of Ecolgy

Dear John R. Williams,

As a concerned consumer I appreciate the opportunity to comment on the reporting rule of the Children's Safe Product Act. The health of the next generation is very important to me and I hope Ecology adopts a strong rule that will:

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* Ensure wide and easy access by the public to information on the chemicals used in specific products.

Thank you for your consideration,

Suzanne Hamer
17227 NE 195th St.
Woodinville, WA 98072

From: Al-Mondhiry, Rend
To: Williams, John (ECY);
Subject: Comments to Children"s Safe Product Act Reporting Rule
Date: Wednesday, December 15, 2010 11:41:35 AM
Attachments: CHPA Comments to WA Safe Children"s Product Rule 12-15-2010.pdf

---

Please see the attached document.

Thank you for your consideration.

Regards,

Rend Al-Mondhiry, Esq.
State Legislative Counsel
Consumer Healthcare Products Association
T 202.429.3537 | M 202.870.7653 | F 866.778.3369
chpa-info.org | OTCsafety.org

Upcoming CHPA event:
Annual Executive Conference | March 10-12, 2011 | The Fairmont Turnberry Isle Resort & Club | Florida

 334

CHPA

founded 1881

December 15, 2010

Mr. John Williams
Waste 2 Resources Program
Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600

By Email

RE: Washington Safe Children's Product Reporting Rule - Chapter 173-334 WAC

Dear Mr. Williams:

On behalf of the Consumer Healthcare Products Association (CHPA), thank you for the opportunity to comment on the proposed Safe Children's Product Reporting Rule, Chapter 173-334 WAC. Founded in 1881, CHPA is a member-based association representing the leading manufacturers and distributors of nonprescription, over-the-counter (OTC) medicines and nutritional supplements.

The proposed rule would require manufacturers of children's products to notify the Department of Ecology if certain high-concern chemicals are present in their products, as required under Washington's Children's Safe Products Act (CSPA), Chapter 70.240 RCW. The CSPA defines the scope of "Children's Products" to include: (i) Toys; (ii) Children's cosmetics; (iii) Children's jewelry; (iv) A product designed or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by children; or (v) Child car seats. RCW § 70.240.010 (3)(a). The Act further defines "Cosmetics" to exclude soap, dietary supplements, or food and drugs approved by the United States Food and Drug Administration (FDA). RCW § 70.240.010 (4). CHPA supports the exclusion of drugs from the definition of cosmetics, as these products are highly regulated by the FDA.

CHPA respectfully requests that the Department adopt a similar definition for "A product designed or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by children", to be included under WAC 173-334-040 of the proposed rule:

> "A product designed or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by children" does not include drugs regulated by the United States Food and Drug Administration.

Consumer Healthcare Products Association
900 19th Street, NW, Suite 700
Washington, DC 20006
T 202.429.9260 F 202.223.6835
www.chpa-info.org

 334

335

OTC children's products, such as those used for teething pain, are regulated by the FDA and undergo rigorous testing for safety and quality. CHPA and its member companies work hard to maintain these high standards and to ensure the safety of children's products. We strongly urge the Department to revise the proposed rule and include the definition as set forth above.

CHPA appreciates the opportunity to contribute to the development of the Safer Children's Product Reporting Rule. Should you have any questions, please contact me at (202) 429-3537 or ral-mondhiry@chpa-info.org.

Sincerely,

Rend Al-Mondhiry
State Legislative Counsel

335
335

From: Guichard, Maryanne (DOH)
To: Williams, John (ECY);
cc: Cooper, Kelly (DOH);
Subject: DOH comments to CSPA rule
Date: Friday, January 07, 2011 3:30:04 PM
Attachments: CSPA rule comments Jan 7 2011(2).docx

John,

Here are our comment regarding CSPA Rule. Please let me know if you have uestions.

Maryanne Guichard, Assistant Secretary
Environmental Health
Washington Department of Health
phone 360-236-3050

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Division of Environmental Health
PO Box 47820 Olympia, Washington 98504-7820

January 7, 2010

TO: John Williams

FROM: Maryanne Guichard, Assistant Secretary

SUBJECT: Department of Health's Comments on Children's Safe Product – Reporting Rule

The Department of Health (DOH) supports efforts to protect children from harmful chemicals and make children's products safer. The Children's Safe Products Act (CSPA) represents an important step toward these goals. The CSPA was developed in response to concerns about possible health hazards from the chemicals found in children's products. There is little publicly available information about the chemicals that are used to make children's products and the CSPA allows the Department of Ecology (Ecology) to collect information to fill in some of the data gaps. The information collected can improve our understanding of possible exposure to and hazard from the chemicals in children's products.

We appreciate the difficult policy choices that Ecology has encountered in developing this rule. We believe several changes to the reporting requirements in the draft rule will improve the usefulness of the information, provide a stronger scientific foundation for selecting appropriate health-protective actions, and help ensure that benefits for children's health are realized. These recommendations are intended to offer a reasonable balance between burden on industry and public health protection.

Recommendations for Improving Data Collection

We believe the following changes to the reporting requirements are necessary for the data collected under the CSPA to provide adequate support for prioritization of chemicals or products, or for assessment of potential hazards to children. Most of these comments relate to WAC 173-334-090 of the draft rule.

1. Reports should include the identities of the specific products that contain Chemicals of High Concern for Children (CHCCs). Knowing the identity of the product makes it

possible to understand the potential for exposure (and therefore potential hazard) from its physical construction, size of component pieces, and how children are likely to interact with it. This can help agencies, manufacturers, and consumers target actions to specific products. In addition, this is important information for consumers and is needed by agencies to ensure that the reported product has been placed in the appropriate product category. The added cost for providing this information would be negligible.

2. Reports should be required for a sufficient number of products to adequately characterize exposure for each product category or product component. The proposed requirement of reporting only the single maximum CHCC concentration per component per product category is unlikely to provide enough information to be able to understand exposure sufficiently well to prioritize product categories or components in a defensible manner. We are aware of the need to balance costs with benefits in government regulations and recognize that the potential costs of reporting for the CSPA could be significant. One or more of the following options could provide better data while keeping costs reasonable:

    a. Require each manufacturer to report the CHCC content of its top selling products in each product category, based on the number of units sold in Washington. This could be the top 10, 25, or 100 best sellers. The number of products reported could be based on the size of the manufacturer. Compared to the reporting scheme in the draft rule, this could lead to a better understanding of exposure to the population of children as a whole.

    b. Require manufacturers to identify the highest concentration of each CHCC in each product category and determine the appropriate concentration range for that product (as defined in the current draft rule). For example, if the CHCC concentration was 5000 parts per million, it would fall in the 1000 to 10000 part per million range. The manufacturer would then be required to report all products with CHCC concentrations that fall in that concentration range (and, perhaps those that fall in the next lower concentration range also). This could result in better understanding of individual and population exposure for children.

    c. Require manufacturers to report all products where CHCCs were added intentionally at some step in the manufacturing process, are part of the design specifications, or are a known process contaminant. From a public health perspective, DOH is interested in knowing the final chemical content of children’s products regardless of the source. For many chemicals, this information should be readily available to the manufacturers and would not require costly testing or data analysis to obtain.

3. Reporting limits should be removed or lowered for many of the CHCCs. Evidence suggests that many CHCCs in children's products will not have to be reported because their concentrations are unlikely to exceed the 40 parts per million reporting limit listed in the draft rule. Several chemicals on the CHCC list may be of health concern at concentrations less than 40 parts per million and it is important to understand the potential for exposure from children's products at those lower levels. If Ecology plans to

specify reporting limits, we encourage Ecology to follow the joint recommendations of DOH and the University of Washington Pediatric Environmental Health Specialty Unit in our July 2010 Phase 3 report.

Additional Recommendations

4. Right-to-know: The legislature intended that data reported under the CSPA be used to inform consumers about CHCCs in children's products. As specified in RCW 43.70.660, the CSPA authorized DOH to establish a public awareness campaign about children's products that contain CHCCs. We believe that consumers should be informed about the presence of CHCCs in specific products, and the reported data collected by Ecology should include the identity of the products tested. Providing product-specific information can help consumers make better purchasing decisions, whereas providing CHCC information about a product category based on a few unidentified samples may be very confusing and cause consumers to inappropriately believe the entire product category is unsafe.

5. Definition of product component: We recommend deleting the word "substrate" from the definition of "product component" (WAC 173-334-040). In the draft California Safer Consumer Product Alternatives regulation, the definition of "component" is limited mostly to things like "pieces" and "parts" that would be identifiable as "unique" on the basis of a visual examination. The definition in Ecology's draft rule includes "substrate" and it's not clear what criteria (visual examination, aroma, chemical analysis, or all of these) would be used to determine whether a substrate is unique. The method of determining the uniqueness of a substrate in a product or product category should be defined if Ecology plans to keep "substrate" in the definition. Also, Ecology should specify what manufacturers have to report if a product component is both a "part" and a "substrate." For example, the arm of a doll (i.e., a part) may be made of PVC (a substrate) with a coat of paint on it. Are manufacturers required to report on unique parts, substrates, or both? The reported component should be the arm of a specific doll which is more distinctive than a PVC or plastic substrate that could be used in many dolls.

6. Manufacturer information: RCW 70.240.040 requires that notices of CHCCs in children's products submitted to Ecology must include the name and address of the manufacturer. Although this does not appear to be included in the draft rule, we recommend that manufacturers be identified in all reports.

7. Cadmium, lead, and phthalates: We recommend that the CHCC list include lead, cadmium, and the six phthalates listed under the federal Consumer Product Safety Improvement Act (CPSIA) on the CSPA reporting list unless they are specifically pre-empted by CPSIA.

Thank you for the opportunity to provide comments on the draft CSPA regulation. If you have any questions, please contact Nancy Napolilli at 306-236-3325 or nancy.napolilli@doh.wa.gov.

From: Grant Nelson
To: Williams, John (ECY);
cc: Sturdevant, Ted (ECY); Kraege, Carol P. (ECY); Terwilleger, Karen (ECY); Manning, Jay (GOV); Justin, Jim (GOV); Phillips, Keith (GOV); Burrell, Kari (GOV);
Subject: Ecology Proposed CSPA Rule - AWB Comments
Date: Friday, January 07, 2011 4:52:26 PM
Attachments: CSPA Proposed Rule - AWB Comments - Jan 7, 2011.pdf

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Hi John,

Please see attached AWB comments regarding Ecology's proposed CSPA rule.

Thank you.

GRANT A. NELSON
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January 7, 2011

John Williams
Department of Ecology
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Olympia, WA 98504-7600

submitted via email: john.williams@ecy.wa.gov

Subject: AWB Comments – Children's Safe Products Reporting Rule

Dear Mr. Williams,

The Association of Washington Business (AWB) appreciates the opportunity to submit the following comments regarding the Department of Ecology's October 22, 2010 draft Children's Safe Products Reporting Rule (Chapter 173-334 WAC).

In addition to the following comments, AWB supports comments regarding the proposed draft and the pilot rule developed earlier this year submitted by the Toy Industry Association, the Grocery Manufacturers Association, Johnson & Johnson, the American Forest Products Association, the American Chemistry Council, the Personal Care Products Council and the American Coatings Association.

Ensuring that products sold in Washington are safe, especially children's products, is critically important. And we believe that with very few exceptions, products that are manufactured for sale in Washington state are indeed very safe. Despite all the media coverage and negative publicity regarding chemicals

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used in products, we also need to remember that chemicals are designed to benefit the consumer, such as increasing the resistance to heat and fire and ensuring plastics are not too brittle, which could lead to a choking hazard for children.

When the Governor vetoed sections of HB 2647 in 2008 which established the CSPA, she made it clear in her veto message that "*...without careful implementation, this bill could adversely affect the availability of safe toys in our state, including important educational toys...*"She also asked Ecology to "*focus on the highest priority chemicals...and those chemicals likely to be found in children's products...*"

Proposed Children's Safe Products Rule Comments

AWB believes that the draft rule is inconsistent with the Governor's direction to Ecology in her veto message, and needs to be amended for the following reasons:

1) The threshold of 40 ppm (.001%, or .00001) is far too low, and beyond the ability of modern testing equipment to accurately measure at that extremely low level. Instead, AWB supports adopting a standard consistent with the European Union of 1,000 ppm (.1%) which has been determined worldwide to be more than adequately protective of human health.

2) The reporting requirements should be limited to those chemicals that a manufacturer intentionally adds to a product. A manufacturer should not be required to test for chemicals that are not part of the product manufacturing or design.

3) The list of chemicals manufacturers are required to report needs trimming. As the Department of Health and the University of Washington reported in July of this year, 27 of the chemicals on Ecology's list are not likely to be intentionally added to products. Those 27 chemicals should therefore be removed from the reporting requirements.

4) The reporting rule should be limited to product components that a child is likely to contact. Internal parts and parts that are inaccessible and not likely to come into contact with children through reasonable and foreseeable use should be exempted from the reporting obligations of the rule.

5) Food and drugs should be specifically exempted from the rule, as those products are thoroughly regulated by the federal Food and Drug Administration.

Preliminary Cost-Benefit and Least Burdensome Alternative Analysis

Ecology has attempted to comply with RCW 34.05.328 by producing a cost-benefit analysis and least burdensome alternative analysis on the proposed CSPA rule. The Department correctly acknowledges that Washington's CSPA law is the first of its kind in the nation and that there is no baseline for comparison. The cost-benefit analysis appears to be largely speculative and yet Ecology concludes that the benefits of the rule will somehow be greater than the projected reporting costs of $44.7-69.5 million over a 20-year period. It is apparent that the Department's rational and conclusions are heavily biased in favor of the proposed rule and alleged benefits, which are very subjective.

With respect to the least burdensome alternative analysis, the five changes to the rule requested in the above comments would result in a rule far less burdensome to those required to report under the rule, while still accomplishing the goals and objectives of the rule. Therefore, in order to adopt a "least burdensome" rule, the above changes need to be incorporated.

Small Business Economic Impact Statement

The SBEIS concludes that the rule will have a disproportionate impact on small businesses, but appears to be for the most part the same language included in the cost-benefit analysis and least burdensome alternative analysis. The SBEIS estimates that the proposed rule is likely to (only) reduce employment in the

state by up to 0.5 positions over 20 years, while compliance costs on businesses have been estimated to be $44.7- 69.5 million over that same 20-year period. Ecology admits that the development of the proposed rule included little to no participation from small businesses, which begs the question whether Ecology consulted with small businesses in the development of the SBEIS.

AWB appreciates the Department's consideration of these comments prior to adopting the final rule. Our members remain committed to ensuring the CSPA rule is implemented in a manner that is both practical and protective of children's health.

Sincerely,

Grant Nelson
Government Affairs Director

cc. Ted Sturdevant, Washington Department of Ecology
Carol Kraege, Washington Department of Ecology
Karen Terwilleger, Washington Department of Ecology
Jay Manning, Office of the Governor
Jim Justin, Office of the Governor
Keith Phillips, Office of Financial Management
Kari Burrell, Office of Financial Management

From: Rothstein, Zachary
To: Williams, John (ECY);
cc: Millar, Sheila A.; BRCleave@aol.com;
Subject: FJATA Comments for the Children"s Safe Product Act - Reporting Rule
Date: Friday, January 07, 2011 1:09:12 PM
Attachments: FJATA Comments for the Children"s Safe Product Act - Reporting Rule.pdf

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Dear Mr. Williams,

On behalf of the Fashion Jewelry and Accessories Trade Association, we submit the attached comments in response to the Washington State Department of Ecology's Children's Safe Product Act – Reporting Rule. Should you have any questions, please feel free to contact me or Sheila Millar, at millar@khlaw.com.

Regards,

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January 7, 2011

Via Electronic Mail jowi461@ecy.wa.gov

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Re: Comments on the Children's Safe Product Act – Reporting Rule

Dear Mr. Williams:

On behalf of the Fashion Jewelry and Accessories Trade Association ("FJATA"), we appreciate this opportunity to submit comments in response to the Washington State Department of Ecology's ("DOE") Children's Safe Product Act – Reporting Rule ("Rule"). FJATA's membership has a strong commitment to consumer safety and includes in excess of 200 companies that manufacture or distribute fashion jewelry in the United States, consisting predominantly of small businesses. Fashion jewelry, like fine jewelry, includes bracelets, charms, earrings, necklaces, pins, rings, and other fashion accessories principally intended to be worn as an item of personal ornamentation. Styles are many and varied, and change multiple times a year, in keeping with fashion trends. Numerous materials may be used in fashion jewelry, including metal (often plated with gold or silver), plastic, enamels, paint, wood, seeds, textiles, and other materials. Fine jewelry may also include a mix of materials. Fashion jewelry suppliers typically offer many different styles in small lots. Jewelry components can include clasps and closures, spring rings, chains of different weights and sizes, beads, charms, pendants and more.

The Rule requires manufacturers of children's products to report annually information concerning the use of substances appearing on the Rule's reporting list. Children's jewelry, defined as jewelry made for, marketed for use by, or marketed to children under 12, is a covered product. RCW 70.240.010(2). The draft regulations thus affect both fine as well as fashion jewelry. Required information includes the name of the substance, description of its function in the product, and the total amount by weight contained in each product (required to be reported within specific designated ranges). Jewelry, including fashion jewelry, is considered a "Tier 2" product under the Rule. As currently proposed, reporting obligations for companies making Tier 2 products that contain "chemicals of high concern" will take effect within 18-72 months of the Rule's effective date, depending on the size of the manufacturer.

Summary of Comments

The Rule implements the Children's Safe Products Act ("CSPA"), requiring reporting on the presence of "chemicals of high concern to children" ("CHCC") in certain children's products, including jewelry, toys and cosmetics. In its current form, the Rule will offer limited, if any, benefits given the extraordinary burdens involved. FJATA urges DOE to modify aspects of the proposed Rule that are duplicative of other regulations, standards and requirements, or will fail to advance the state of scientific knowledge about the use of a particular substance in children's products.

Children's products are currently regulated by the U.S. Consumer Product Safety Commission ("CPSC") under the Consumer Product Safety Improvement Act of 2008 ("CPSIA") and other statutes administered by CPSC, including the Federal Hazardous Substances Act (FHSA). In addition, a safety standard is being developed to address specific heavy metals, including cadmium, in children's jewelry through ASTM International. FJATA and CPSC have independently tested jewelry for cadmium, looking at both total and migratable cadmium. The data illustrate the difficulty in developing a firm total content limit from a safety standpoint, as even products with high total cadmium may release very low levels of migratable cadmium. Consequently, it is not apparent how reporting, especially at the levels proposed, will fill any "data gaps" or advance the ongoing process of developing a science-based standard for cadmium in jewelry.

To the extent the Rule moves forward, DOE should minimize its burden on small business and the state by taking the following key actions: 1) Adopt a complete exclusion from reporting for naturally occurring substances present in products; 2) establish *de minimis* reporting thresholds for substances appearing on the reporting list, subject to revision through a science-based process; 3) exclude from the requirements reporting on components, like crystal, known to result in very low migration of constituent substances; and 4) revise the list by adopting a risk-based approach to setting priorities for listing and focusing on substances known to cause adverse health effects. Such policies would reduce the otherwise burdensome compliance costs associated with product testing and reporting.

I. Substances Being Addressed in Other National Venues

Similar to DOE's determination for lead and phthalates, cadmium should be removed from the reporting list. Cadmium was not included in the original reporting list because DOE understood it was being addressed at the federal level. However, the current version of the reporting list includes cadmium, apparently because "CPSC has not developed rules to address cadmium as promised when the [CPSIA] was passed." DOE Pilot Rule Development Process, p. 4. This statement does not accurately reflect the current regulatory status of cadmium in jewelry. CPSC recently solicited comments pursuant to a petition from the Sierra Club concerning cadmium content in children's jewelry, and, in cooperation with FJATA, has been working to

establish a voluntary children's jewelry safety standard through ASTM International. DOE's initial determination was correct that additional regulations need not be placed on cadmium by the State due to the development of a national standard. Cadmium, therefore, should be removed from the reporting list.

In addition, reporting on cadmium will not advance the state of understanding of the presence of cadmium in children's jewelry. Cadmium in jewelry has been well-studied in research by FJATA and CPSC over the past year, as the enclosed reports indicate. For example, a review of the recent CPSC report on cadmium in jewelry[1] emphasizes the CPSC's support for a migration approach. In the CPSC's tests, children's jewelry components containing cadmium in concentrations of 1.35% or less never released migratable cadmium at levels remotely harmful, even using a worst-case scenario, 24-hour ingestion test method. This data is very consistent with FJATA's own research on the typical size and shape of jewelry components.[2] Notably, based on this research, an average migration rate can be derived, per the attached report; this data is currently being evaluated by the ASTM committee developing a children's jewelry safety standard. This standard is expected to be finalized for balloting very soon.

DOE would not "fill a data gap" by requiring makers of children's fashion jewelry to report on an annual basis information about cadmium, certainly not at every content band proposed. DOE should utilize its resources more efficiently by excluding from the reporting obligations substances that may be present in fashion jewelry but are being addressed elsewhere through national standards.

II. Naturally Occurring Substances

Several substances on the reporting list occur naturally in soil and in rocks, and are therefore found with ores used in materials incorporated in fashion jewelry. These substances are often present, typically in trace amounts, in metal components, including base metals like zinc or tin; or plating metals, such as copper, nickel, sterling silver, or karat gold. Thus, trace amounts of naturally occurring chemicals may be present in metals used to make jewelry, even where they are not intentionally added.

DOE should adopt a categorical exclusion from the reporting requirements for any listed substances that are *not intentionally added* to a covered product. The plain language of the

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[1] *See* Consumer Product Safety Commission Staff Report: Cadmium in Children's Metal Jewelry, October, 2010, *available at* http://www.productsafetyletter.com/newspics/cadmium_F15.24_jewelry.pdf.

[2] A wafer sample of a sort not typical of a standard jewelry shape or configuration was tested to evaluate whether migration rates were similar to migration rates of sample jewelry components in tests sponsored by FJATA. While migration rates were similar, these tests did yield somewhat higher levels of migratable cadmium.

authorizing statute suggests that reporting was intended to be required only for chemicals intentionally added to the product. The CSPA requires a manufacturer to report "[t]he name of the chemical *used or produced*" in a consumer product, and "the *function* of the chemical in the product." RCW 70.240.040(1), (3) (emphasis added). As this language suggests, the unintentional presence of a chemical does not trigger the reporting obligation because it is not used or produced in the manufacture of the product, nor does it serve a particular function which could be the subject of reporting. *See* DOE Pilot Rule Development Process, p. 2 (explaining that contaminants "do not provide any functional purpose in the product."). Accordingly, DOE should exempt from the reporting requirements substances not intentionally added to the product. This position would be consistent with DOE's assessment in its Phase 3 report, which noted that "for practical reasons, the focus should be on those chemicals that are intentionally added to children's products. By focusing on these [intentionally added] chemicals we can better use our limited resources."

Moreover, reports on the presence of naturally occurring trace contaminants will not provide DOE with a better understanding of a product's safety, as "the mere presence of chemicals of concern in a children's product does not mean that exposure to those chemicals is occurring, nor does it mean that the product is unsafe." DOE Pilot Project Executive Summary, p. 1. Thus, there is no basis to conclude that information concerning the presence of naturally occurring contaminants will lead to increased safety awareness.

III. *De Minimis* Reporting Thresholds

The January 22, 2010 draft version of the Rule appropriately indicated that a reporting threshold would be identified for chemicals on the reporting list. DOE's Phase 3 Report reiterated this position, stating that "concentration of chemicals of concern present at 0.1% in product components is a commonly accepted value, used by jurisdictions such as the European Union, to indicate that a chemical is intentionally added to a product . . . Ecology chose to bracket reporting ranges around the commonly used value of 0.1%." However, the current version of the Rule utilizes reporting thresholds below this commonly accepted *de minimis* amount, requiring manufacturers to report on the presence of any amount of a chemical appearing on the reporting list in ranges from 40 – 200 ppm (0.004 - 0.02%) and from 200 – 1,000 ppm (0.02 - 0.1%). There is no appropriate public health protection rationale for reporting on the presence of substances at these low levels across the board, and no explanation or justification for why the Department moved away from its earlier policy in adopting these very low reporting thresholds.

De minimis thresholds should be adopted for all substances on the reporting list, with a default level of 0.1%, to be revised by DOE through a chemical specific, scientific process. In addition, section WAC 173-334-090(e)(i)-(v), which requires content amounts be reported within specific, narrow ranges, should be deleted as compliance costs would prove too burdensome. A reporting threshold of 0.1% by weight should be the trigger for reporting under the Rule. This

threshold reflects the European Union's REACH legislation and Section 313 of the Superfund Amendments and Reauthorization Act, therefore, simplifying the reporting process considerably and helping maintain consistency throughout the regulating and regulated community. For example, antimony is an essential component used in making crystal, where it is present at less than 0.1%. Metals like antimony bind to the crystal matrix and do not migrate readily; adoption of a *de minimis* threshold will eliminate a reporting burden for jewelry companies that use crystal.

IV. Exclusion for Certain Components

Under the draft proposed rule reports must be submitted on a component basis. Because of the many different components used in fashion jewelry, component reporting is especially burdensome. Extensive testing for lead and other substances in crystal demonstrate that these materials are bound into the crystal matrix and do not migrate readily. In fact, migration of lead from crystal containing lead at 24% or higher (which meets regulatory definitions of "crystal" in Europe) was less than migration of lead from other materials that met federal lead limits. Testing for total heavy metals in crystal requires use of a hydrofluoric (HFl) acid solution because dissolution of the glass matrix cannot be achieved without this more aggressive acid. Many laboratories will not use HFl because of safety and environmental disposal considerations. We therefore urge excluding crystal and similar components from reporting.

V. Risk-Based Priorities

In an era of increasingly limited state resources, DOE should focus on the substances and potential exposures likely to have the most significant impact on children's health, avoiding, as noted above, duplicating standards or requirements set forth in existing laws or third-party consensus safety standards or imposing reporting burdens on substances in children's products that are already well-studied.

DOE should adhere to the following three rules when determining to list a particular substance:

- Only chemicals presenting *known* hazards should be listed; "suspected" or "presumed" toxics should not be included. Further, substances should be listed based on documented evidence regarding the potential route of exposure relevant to the reporting obligations in terms of potential exposure of children to the CHCC. In other words, a substance listed solely as an inhalation toxic in a product, like jewelry, where inhalation exposure is not expected, should not trigger mandatory reporting.

- The listing must be from an authoritative source, meaning a source that is both credible and reliable. Sources relied upon for listings must be completely transparent and publicly searchable.

- In prioritizing listed substances, DOE should include an assessment of those likely to pose the most significant potential health threat to children through an examination of exposure, use and hazard data, identifying substances likely to pose the most severe hazards, not otherwise being addressed on a national basis, first.

VI. Compliance Costs

DOE has estimated that compliance costs associated with the Rule will range from $1,000 to $10,000 per year for a manufacturer of children's products. It is in fact not clear that this rule is the least burdensome version for those required to comply. For example, while DOE stresses that testing will not be required, it fails to explain how compliance, except through testing, will be achieved by an annual reporting scheme that requires per component reporting for 59 listed substances and a demonstration of due diligence. The draft rule also appears to offer companies who actually conduct alternative assessments to avoid reporting, but the reporting thresholds make doing so almost impossible as a practical matter.

The Preliminary Cost-Benefit and Least Burdensome Alternatives Analysis, and the Small Business Economic Impact Statement both stress that testing is not required for compliance, but the draft rule does not clearly establish that chemical and/or material self-declarations is an acceptable alternative to product testing, and does not categorically exclude reporting of the naturally-occurring levels or *de minimis* content. In fact, WAC-173-334-130(2) includes an explicit reference to testing as part of a manufacturer's due diligence:

> Actions demonstrating diligence may include the use and enforcement of contract specifications, procedures to ensure the quality/purity of feedstock (whether raw or recycled), the use and enforcement of contract specifications for manufacturing process parameters (e.g., drying and curing times when relevant to the presence of high priority chemicals in the finished children's product components), *periodic testing for the presence and amount of CHCCs,* auditing of contractor or supplier manufacturing processes, and other practices reasonably designed to ensure the manufacturer's knowledge of the presence, use, and amount of CHCCs in its children's product components (emphasis added).

The draft rule thus still suggests that affected children's jewelry manufacturers may in fact have to test all product components for all listed substances, even if just to prove the absence of a listed substance from the many components that might be found in the various jewelry items they

may be responsible for annually, so as not to be found lacking in due diligence. Costs are likely to be high.[3]

Similarly, proposed WAC 173-334-120(5) establishes that a manufacturer who provides documentation that it is conducting a safer alternatives assessment intended to result in the elimination or a substantial reduction of CHCCs in its products may be granted a 12 month reporting extension by the Department, but if, despite the reduction, the specified chemical is present in any component in the product category in amounts as low as 40 ppm, reporting appears to nevertheless be required. Again, the public policy and public health benefits do not appear to outweigh the burdens associated with such reporting. The statute explicitly allows for reporting in ranges, an approach reflected in the proposed rule, but does not mandate the specific ranges proposed. The Department, by establishing the lowest reporting threshold of 40 – 200 ppm, has apparently adopted a *de minimis* threshold, but one that is unrelated to traditional *de minimis* thresholds widely used in other contexts. Use of these reporting ranges thus assures that the burden of reporting remains even where chemical reductions occur. FJATA again urges DOE to adopt a default *de minimis* exclusion of 0.1% (1,000 ppm) from reporting, and an exclusion for naturally occurring chemicals to minimize undue burdens on industry.

VII. Conclusion

FJATA urges DOE to reconsider moving forward with the Rule. The Rule currently includes duplicative obligations on children's fashion jewelry manufacturers, as the industry is already regulated at the federal level and is in the process of developing a voluntary third-party safety standard to address heavy metal content for metals such as cadmium. DOE should review the current list of substances to confirm that they reflect appropriate children's health priorities. Only chemicals presenting known hazards should be listed, and those substances should be listed based on documented evidence that the toxic hazard is associated with a potential route of exposure relevant to potential exposure of children to the CHCC in an actual consumer product.

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[3] CPSC recently conducted an economic impact analysis of the burdens placed on small businesses for product testing requirements. The report confirms that testing costs for even small manufacturers can easily reach hundreds of thousands of dollars per year, depending on the number of products offered for sale and the type of tests that are performed. For example, CPSC reported that lead tests range from $50-$100 per test; phthalates testing ranges from $100 (a discounted price by a laboratory in China) to about $350 per test; and heavy metal testing ranges from about $60-$190 per surface coating. CPSC Proposed Rule, Testing and Labeling Pertaining to Product Certification, 75 Fed. Reg. 28,336, 28,355 (May 20, 2010), *available at* http://www.cpsc.gov/businfo/frnotices/fr10/testing.pdf. These estimated costs simply involve two chemicals, not 59 different substances.

Moreover, recent studies by CPSC and FJATA on cadmium in jewelry leave little to no new information to be gleaned by DOE through the annual reports at the total content bands suggested. FJATA urges that the list exclude cadmium in jewelry as a result. Should DOE move forward with the Rule, it should categorically exclude naturally occurring substances from the reporting obligations, exclude materials, like crystal, known to bind substances like heavy metals into the matrix, and establish true *de minimis* reporting thresholds to mitigate the costs and burdens associated with compliance.

FJATA appreciates the opportunity to submit these comments.

Sincerely,

Sheila A. Millar

cc: Brent Cleaveland, Executive Director, FJATA

Enclosure

354

354

Health Sciences

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Technical Report

Evaluation of Cadmium in Metal Jewelry

354

354

Exponent®

Technical Report

Evaluation of Cadmium in Metal Jewelry

Prepared for

Fashion Jewelry and Accessories Trade Association
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November 2010

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Contents

Page

Introduction **1**

Description of Testing **2**

Sample Preparation 2

Analytical Testing 2

Relevance of Testing Methods for Exposure Assessment 3

Considerations When Performing Corrosion Tests in Simulated Environments 3

Gastric Transit Time 5

Levels of Extractable Cadmium from Metal Jewelry **7**

Heart and Winged Circle Samples 7

Wafer Samples 10

Exposure Assessment Considerations **12**

Conclusions **15**

Tables
Photographs

Introduction

This report describes an evaluation of potential exposure to children related to the cadmium content of metal jewelry based on recent cadmium testing results. Jewelry, as defined in this report, is a product principally designed and intended as an ornament to be worn by a person.

We are not aware of any published literature regarding extractable levels of cadmium from metal jewelry, nor are we aware of any published, peer-reviewed data linking the use of cadmium in metal jewelry, or human exposure to cadmium in jewelry, to any health effects. Various tests have been conducted, some by the Consumer Product Safety Commission (CPSC), to determine the leachable concentrations of cadmium in paint and coatings, and in limited instances, leachable levels from metal jewelry products. Additionally, few data are available on the relationship between the total content of cadmium in jewelry products and the bioavailable concentrations of cadmium should it be ingested (i.e., the fraction that could migrate from the jewelry and be taken up by the human body, or the "migratable" concentration). In an attempt to gather this type of information, the Fashion Jewelry & Accessories Trade Association (FJATA) commissioned third-party testing of various metal jewelry samples by an independent laboratory to evaluate this issue. The testing methods and results, along with interpretation of the testing data are provided in this report.

Description of Testing

Sample Preparation

Three tin alloys containing cadmium at levels of 1%, 5%, and 10%, and a zinc alloy with 1% cadmium, were prepared. The alloy supplier had difficulty preparing such small batches, because the cadmium levels were difficult to quantify. Therefore, higher concentrations than what would be typically found in children's jewelry products were generated in the sample to ensure accurate cadmium quantification. Once the alloys were generated, samples were cast into a disc wafer, a heart, and a winged circle. The zinc alloy was molded into a cone shape. The samples are shown in Photo 1 (photographs are presented following the text).

One jewelry sample was left unplated, and plating finishes were applied to the other two, at "economy" and "quality" levels.[1] The "quality plate" started with a vibratory finishing step to prepare the surface to accept the plating. Then the process continued with an acid copper flash, 5–7 mils palladium, and 10 mils gold. The "economy plate" also started with the vibratory process, followed by the acid copper flash, an imitation rhodium flash, and then 2–3 mils gold.

Analytical Testing

The following types of testing were conducted on each sample:

- Total cadmium content—EPA Modified Method 3050B/3051.
- EN-71—Based on the principle that soluble elements are extractable from toys under conditions that simulate a scenario wherein the material stays 4 hours in the alimentary tract after being swallowed. The sample is subjected to an acidic extraction solution of 0.07 mol/L hydrochloric acid that is shaken for one continuous hour, followed by standing for another hour.
- Six-hour leaching test—A sample is suspended in 0.07 N hydrochloric acid solution with a volume equal to 50 times the component weight for 1, 2, and 3 hours at 37 °C with agitation. After each time interval, the extractant is decanted, and fresh extractant is added. The sample is thus exposed to 6 hours of extraction.
- Twenty-four-hour static leaching test—A sample is suspended in 0.07 N hydrochloric acid solution with a volume equal to 50 times the component weight for 24 hours, with no agitation.

[1] Jewelry is rarely sold or distributed with metal components that are "raw," or unplated. Some very inexpensive premiums and products made with pewter would be examples of unplated products.

- Twenty-four-hour agitation leaching test—A sample is suspended in 0.07 N hydrochloric acid solution with a volume equal to 50 times the component weight for 24 hours, with shaker-bath agitation.

Relevance of Testing Methods to Exposure Assessment

There is general agreement that, for items such as children's jewelry, a worst-case scenario involves ingestion. Thus, to evaluate the potential exposure should a child accidently ingest a jewelry component, the tests must be designed to assess the behavior of the materials in simulated stomach acid. The conditions of the test, including the temperature, pH, duration of exposure, and whether the test is conducted under dynamic versus static conditions, may dramatically affect test results, so it is important to identify test conditions that are reasonable and appropriate to evaluate products and materials in this environment.

Considerations When Performing Corrosion Tests in Simulated Environments

Corrosion testing is a useful tool to help understand corrosion mechanisms and corrosion rates of various materials in simulated environments. Because corrosion of a material is dependent on the specifics of exposure, it is very important to model the in-service (or actual use) environment as closely as possible when performing laboratory experiments. Parameters to consider when selecting an environment include the solution to which the part is exposed (electrolyte), temperature, aeration, pH, duration of exposure, and velocity of solution (i.e., stagnant vs. flowing) (Metals Handbook 1987). Attempting to accelerate a test by creating aggressive conditions may or may not yield useful information about the actual corrosion behavior of the material in service, because unrealistic test conditions may activate corrosion mechanisms that would not otherwise occur in service.

The current test method for evaluating potential exposure of children to heavy metals in toys, per EN-71, is an immersion-type test intended to assess the leachability of the constituent elements in the piece while it is subjected to conditions that would be encountered if the part were ingested. This is a short-duration test (2 hours or less) that includes agitation during part of the exposure period; it is intended to mimic conditions in the stomach using a test temperature that reflects body temperature (see discussion below on gastric transit time). EN-71 is a widely accepted, internationally peer-reviewed method used to evaluate potential exposure of children to heavy metals in toys if the toy is mouthed or ingested. It is now a mandatory test requirement for evaluating heavy metals in surface coatings of toys by virtue of the adoption of ASTM F-963 through the Consumer Product Safety Improvement Act of 2008 (CPSIA). This method has been adopted for use by jewelry manufacturers.

In prior evaluations of metal jewelry for purposes of assessing leachable lead content, the CPSC used a 6-hour test, using 1-, 2-, and 3-hour exposure periods under constant agitation (shaking). A proposed alternative test is an even longer duration immersion (24 hours) with constant

agitation. The potential differences in corrosion behavior of a part subjected to these different conditions will be discussed below.

The type of costume jewelry evaluated by this test method is typically a low-temperature casting alloy that is typically plated with another metal or combination of metals. Charms and other ornaments may be attached by clasps or rings (which can be removed and tested separately), or they may be firmly attached through soldering. Solder joints may be present even without the presence of external ornaments.

Various types of corrosion can occur in these designs, depending on the conditions of use. The parts may experience general corrosion (i.e., relatively uniform wasting or dissolution) as a result of exposure to the environment. Crevice corrosion can occur as a result of geometry. When parts are joined or shaped such that small crevices occur, corrosion within the crevices may be enhanced. This is because the environment within the crevice can differ significantly from the bulk environment (Metals Handbook 1987; Jones1992).

In addition, galvanic corrosion may occur when dissimilar metals or alloys are joined together (Metals Handbook 1987). This could potentially occur at solder joints where pieces are joined using solder of a different alloy than the base metal, or where plating materials differ from the underlayment metal. In addition, plated or coated samples may experience galvanic corrosion if the metal plating contains pores or gaps. If a gap or hole exists in the coating and the underlying material is exposed, a galvanic cell can be established between the substrate and the electroplated coating, typically also made of metal alloys or a series of metals. If the coating is more noble (i.e., more passive, or less reactive, typical with coatings of gold or silver) than the substrate, the substrate will corrode preferentially. If the substrate is more noble than the coating, then the coating will be dissolved preferentially. It is more common with jewelry, however, for the “noble” metal to be the plating material.

Corrosion testing is often performed using “worst-case” conditions, to conservatively bound the results or to accelerate testing. It is therefore very important to consider whether the “worst-case” variables actually create an unrealistic environment vis-à-vis anticipated corrosion behavior in the particular environment of concern. It is our understanding that CPSC’s proposed test would extend the testing duration to 24 hours and include constant shaking of the test vial. These conditions would almost certainly lead to higher measured corrosion rates, for a number of reasons, which may or may not be realistic for the conditions this test is meant to assess, in part because peristalsis in the human gastrointestinal tract is not expected to be continuous for 24 hours.

When a metal or alloy corrodes, an oxide is formed (the corrosion product), which may build up on the surface of the part. With time, this oxide layer may actually act as a barrier to further corrosion. Under these conditions, the corrosion rate would tend to decrease with time as the oxide builds up. Active and constant agitation of the part within a test vessel could dislodge this oxide, allowing constant exposure of fresh metal surface to the test environment. This would have the effect of significantly enhancing overall corrosion rates as compared to a static or partially static test.

Constant aggressive agitation would also continually introduce oxygen into the solution, which could also increase the corrosion rate. If the geometry of the part tested included a crevice, active aeration of the test fluid could lead to an even greater disparity of environments between the crevice and the bulk solution, leading to greater corrosion than what would occur under either stagnant conditions or under conditions that include periods of agitation and periods of stagnation.

If these conditions (aggressive agitation and aeration) are not an accurate model of the environment, then this test method may yield corrosion (and metal leaching) rates that are not good indications of what may actually occur in the environment of concern—the stomach.

Gastric Transit Time

Gastric transit times have been measured using radio-labeled food in different age groups. Graff et al. (2001) investigated the effects of age and gender on transit times through parts of the gastrointestinal tract, including gastric mean transit times. They used radioactively labeled solid food and found that mean gastric transit time was 1.3 to 1.8 hours in 16 young adults (20–30 years old) and 1.9 to 2.3 hours in 16 mature adults (38–53 years old). Bode et al. (2004) investigated gastric emptying and small-intestine transit time in 10 preterm infants (mean age of 28.9 weeks) using radioactively labeled food administered by a naso-gastic tube. The authors reported that gastric small intestine transit time in this study population was 3.1 hours (1.3–6.1 hours).

Maes et al. (1995) measured the relation between gastric emptying rates as a function of energy intake and age group. They reported median gastric emptying half-times for children (15 individuals, mean age 9 years) of 58 minutes for a low-calorie meal, 91 minutes for a high-calorie meal, and 86 minutes for liquid milk. They found no significant difference between children and adults in the emptying rate of the low- and high-calorie meal, but a significantly faster emptying rate was found in the adults for the milk test meal. Singh et al. (2006) monitored gastric emptying of radioactively labeled solid food in 24 children (5 to 10 years). The authors reported that mean half-time for gastric emptying was 107.2 minutes (54.6–159.8 minutes).

Gastric transit time has also been measured using wireless capsule endoscopy (CE). Ge et al. (2006) evaluated the safety of CE in 15 pediatric patients (less than 18 years) with suspicious small-bowel disorders. They reported that the median gastric transit time measured by CE was 85 ±90 minutes. In a similar study, Ge et al. (2007) evaluated the results and safety of CE in pediatric patients using 16 children and adolescents compared to 15 adults. The authors reported a median gastric transit time of 83.5 minutes (4–296 minutes). They stated that there was no significant difference in excretion of capsule and gastric transit time between the pediatric patients and adult patients ($p > 0.05$).

Extraction times used in bioaccessibility studies are designed to simulate portions of the gastrointestinal tract. Ruby et al. (2002) reported the gastric transit time used in six *invitro* extraction studies (including their own) for hydrophobic organic compounds in soil. The gastric transit times ranged from 1 to 3 hours, with three studies using 2 hours. The bioaccessibility test that the authors performed utilized a gastric extraction time of 1 hour, stating that it was

representative of stomach residence time. Macgregor et al. (1998) suggested that transit times for foreign objects to be passed from the body may be variable, but did not recommend a specific stomach residence time. Studies of gastric emptying times, however, are useful as indicators of active peristalsis, suggesting that 6- or 24-hour procedures using constant shaking or agitation are not representative of conditions in the body.

Levels of Extractable Cadmium from Metal Jewelry

Table 1 provides the total content, EN-71, 6-hour, 24-hour static, and 24-hour agitated cadmium results for the approximate 1% (10,000 ppm), 5% (50,000 ppm), and 10% (100,000 ppm) added cadmium samples. The total extractable cadmium in micrograms (µg), sample weight (grams), and concentration converted to ppm (µg/g) are presented. Also presented is the percent extracted based on the total content to extracted concentration. Results for each of the various samples are discussed below. As previously indicated, the use of the 1%, 5%, and 10% samples provide worst-case results and are not representative of typical children's jewelry products that comply with regulations. Rather, data were used to determine resultant potential leachable concentrations for products that contain lower total cadmium levels, and to establish a total content value that would yield acceptable leachable concentrations.

Heart and Winged-Circle Samples

The heart and winged-circle samples represent the most realistic product samples, because they are plate-finished products in a representative jewelry shape. With regard to samples containing approximate 1% added cadmium, the following observations are made:

1. The EN-71 tests were produced non-detect cadmium levels at a detection limit of 1 mg/kg
2. Total extracted cadmium in the 6-hour test ranged from <1 µg (quality plated heart) to 6.1 µg (economy plated winged circle)
3. Total extracted cadmium in the 24-hour static test ranged from 4.5 µg (quality plated heart) to 28.1 µg (economy plated winged circle)
4. Total extracted cadmium in the 24-hour agitated test ranged from 54 µg (quality plated heart) to 116 µg (economy plated winged circle).

In general, more cadmium was extracted from the economy plated samples than from the quality plated samples. However under the worst-case 24-hour agitated test scenario, the percent dissolved was fairly consistent regardless of the type of plating ranging from 0.21% to 0.25%.

Results of the approximate 1%, 5%, and 10% added cadmium samples for the 24-hour agitated test were plotted against the associated total content concentration, in Figure 1 (winged circle) and Figure 2 (heart). The fitted linear models indicate significant slopes with high R^2 values for both these sample types, which supports use of these linear models to predict the 24-hour agitated cadmium concentrations at lower levels more typical of those likely to be observed in metal components of children's jewelry.

The evaluation indicates that the predicted 24-hour leachable cadmium levels for a 3000-ppm and 6000-ppm total content plated 2-gram heart or winged circle jewelry sample (representative product) ranges from 29.8 to 85.4 µg.

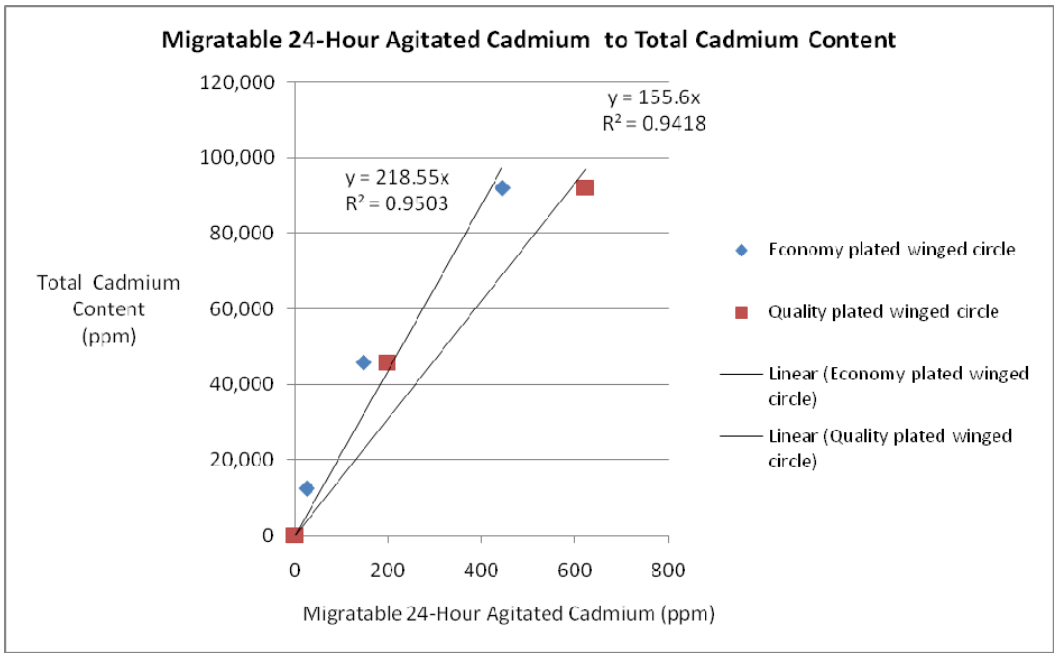

Figure 1. Regression analysis for plated winged circle

Predicted with regression equation for economy plated winged circle

24-hour agitated (µg/g, ppm)	Total Content (ppm)	Predicted total (µg) (for 2-gram sample)
0.5	100	0.9
1.4	300	2.7
2.7	600	5.5
4.6	1000	9.2
13.7	3000	27.5
27.5	6000	54.9

Predicted with regression equation for quality plated winged circle

24-hour agitated (µg/g) (ppm)	Total Content (ppm)	Predicted total (µg) (for 2-gram sample)
0.6	100	1.3
1.9	300	3.9
3.9	600	7.7
6.4	1000	12.9
19.3	3000	38.6
38.6	6000	77.1

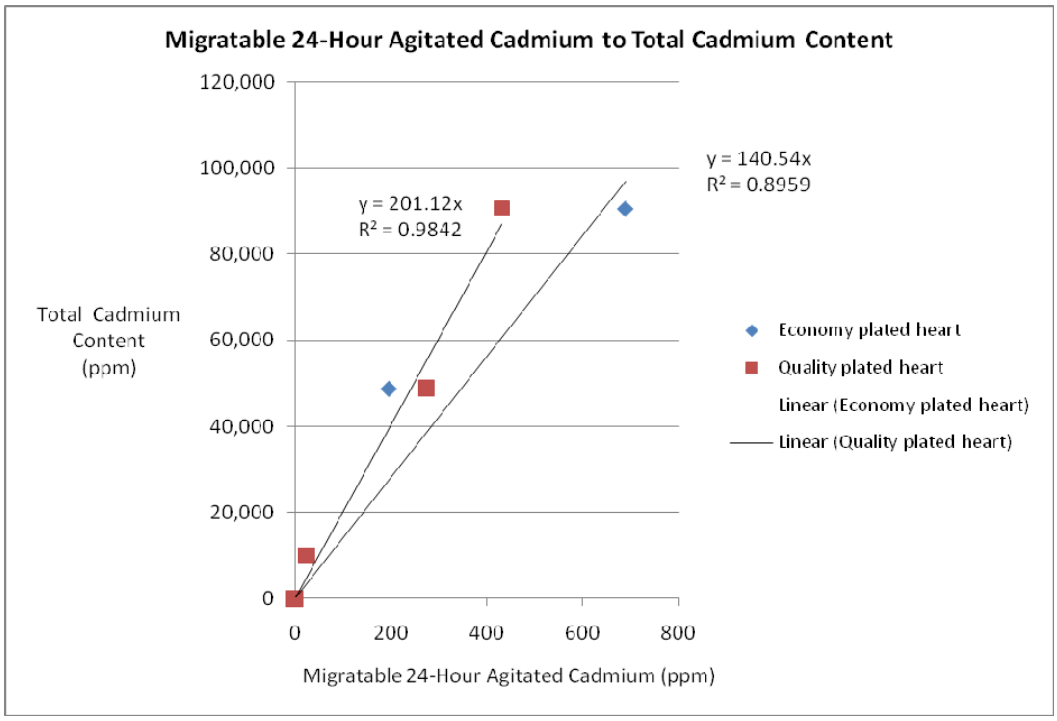

Figure 2. Regression analysis for plated heart

Predicted with regression equation for Economy plated heart

24-hour agitated (µg/g, ppm)	Total Content (ppm)	Predicted total (µg) (for 2-gram sample)
0.7	100	1.4
2.1	300	4.3
4.3	600	8.5
7.1	1000	14.2
21.3	3000	42.7
42.7	6000	85.4

Predicted with regression equation for Quality plated heart:

24-hour agitated (µg/g, ppm)	Total Content (ppm)	Predicted total (µg) (for 2-gram sample)
0.5	100	1.0
1.5	300	3.0
3.0	600	6.0
5.0	1000	9.9
14.9	3000	29.8
29.8	6000	59.7

Wafer Samples

The wafer samples do not represent a finished jewelry shape and are less consistent in their overall shape and surface area. Larger samples were used to conduct the 24-hour agitated leaching tests, and higher amounts of cadmium were released. However, when standardized to µg/g, the percent dissolved for the economy or quality-plated wafer samples (0.21%) was essentially the same as the plated heart and winged circle range (0.21% to 0.25%).

The regression analysis based on the wafer sampling is provided below. As with the plated heart and winged circle samples, the fitted linear models indicate significant slopes with high R^2 values, supporting the use of these linear models to predict the 24-hour agitated cadmium results for lower total content cadmium concentrations.

The evaluation indicates that the predicted 24-hour leachable cadmium levels for a 3000-ppm and 6000-ppm total content plated 2-gram non-representative jewelry shape (worst-case sample) ranges from 24.8 to 49.7 µg.

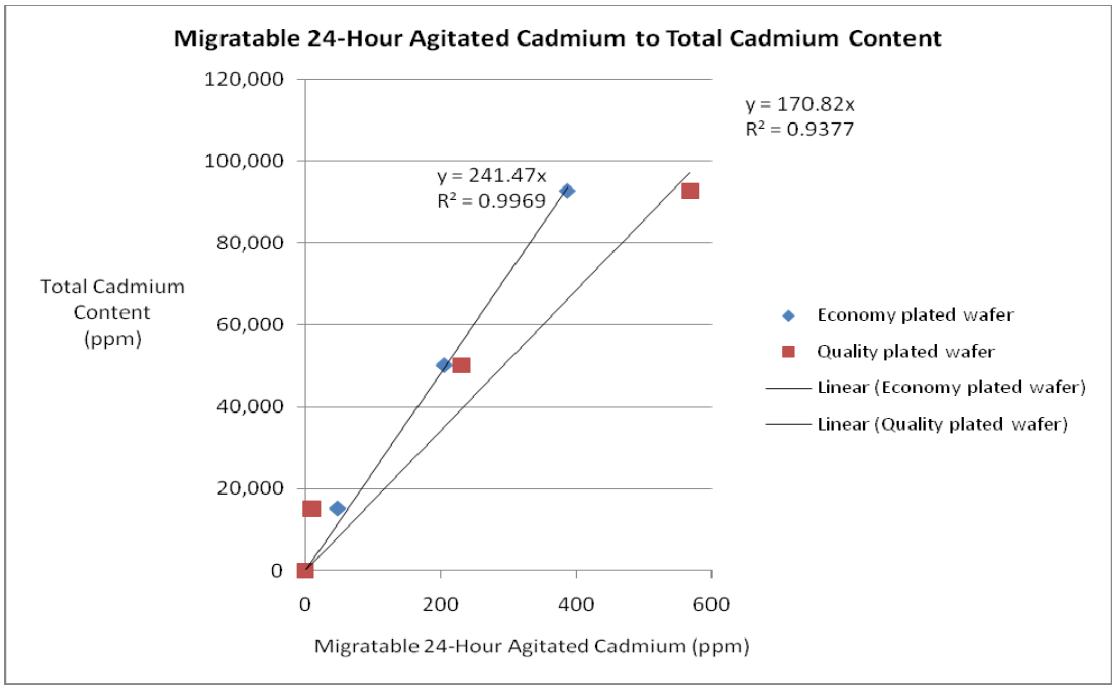

Figure 3. Regression analysis for plated wafer sample

Predicted with regression equation for economy plated wafer:

24-hour agitated (µg/g, ppm)	Total Content (ppm)	Predicted total (µg) (for 2-gram sample)
0.4	100	0.8
1.2	300	2.5
2.5	600	5.0
4.1	1000	8.3
12.4	3000	24.8
24.8	6000	49.7

Predicted with regression equation for Quality Plating Wafer:

24-hour agitated (µg/g, ppm)	Total Content (ppm)	Predicted total (µg) (for 2-gram sample)
0.6	100	1.2
1.8	300	3.5
3.5	600	7.0
5.9	1000	11.7
17.6	3000	35.1
24.8	6000	49.7

Exposure Assessment Considerations

Under an accidental ingestion scenario, it is highly implausible for 100% of a given element in an item to be released and become available for uptake in the body. The available migration data on cadmium suggest that migration rates for plated metal jewelry products, even under aggressive conditions (24-hour agitated), are typically less than 0.5%, and are approximately five times less when tested under 24-hour static conditions (avg. 0.1%; see Table1). Over a more realistic 6-hour time period, the migration level is 0.03%. As previously discussed, aggressive agitation and aeration in the 24-hour test likely yield cadmium migration concentrations that are not good indicators of what may actually occur in the environment of concern—the stomach. Therefore, use of the 24-hour agitation method likely yields an overly conservative "migratable" concentration to be used as a comparison to any toxicology criteria.

Recent data obtained from CPSC (Table 2) also confirm a low migration rate for a variety of products. Although component-specific information was not presented in the report (i.e., which components were plated, type of plating), the CPSC report confirms FJATA findings that use of coatings has a larger effect on cadmium migration than does total cadmium content. Additionally, alloys containing zinc were found to leach less cadmium, suggesting that migration of cadmium may be highly dependent on the type of allow in which it is bound.

As shown in Table 2, the average percent migration of cadmium based on CPSC data is 0.38% for the 24- hour test using 0.07N HCl (a solution that simulates gastric acid) for a variety of CPSC-tested products with total cadmium contents ranging from 0.0285 % (285 ppm) to 99% cadmium. Using migration data based on a 6-hour time period and 0.9% NaCl (a solution that simulates saliva), the average percent migration is 0.08%. These data confirm that an average percent migration of 0.5% is a reasonable assumption based on a wide variety of products tested with very high total cadmium contents. Total cadmium content in children's jewelry will typically be much lower than those sampled in both the FJATA and CPSC testing programs. However, even under these worse-case testing conditions, the data indicate that the overall amount of cadmium migrated from the products is low.

Although it is expected that the relationship between total cadmium content and migratable elements will differ based on such considerations as surface area, size and alloy composition, a general range of total migratable cadmium can be determined based on the information presented here, as well as that provided in the CPSC Staff Report. By applying a reasonable assumption of the percentage of material that will be released based on the total mass of the product sampled and the total cadmium content, the total migratable cadmium can be predicted as follows:

$$\textit{Product mass (grams)} \times 1{,}000{,}000 \times \textit{\% dissolved}/100 \times \textit{wt \% component}/100 = \mu g \textit{ dissolved}$$

For example, the expected migration of cadmium from plated metal jewelry components based on a total cadmium content of 2,000 ppm and various component weights, would yield the following migratable cadmium levels using an assumed migration rate of 0.5%. A representative jewelry component weight is approximately 2 grams.

Expected Migration of Cadmium from Plated Metal Jewelry Components

Component Weight (g)	Total Cadmium Content (ppm)	Assumed Migration Rate (%)	Migratable cadmium (µg)
1 2,000		0.5	10
2 2,000		0.5	20
3 2,000		0.5	30
4 2,000		0.5	40
5 2,000		0.5	50
10 2,000		0.5	100

Even when using the maximum 24-hour agitated percent migration of 2.53% (based on an unrepresentative unplated product) and a total cadmium concentration of 2,000 ppm (0.2%) for a 2 gram component sample, the amount of migratable cadmium yielded is 101 µg. In all instances, the migratable cadmium is below the CPSC recommended maximum allowable acute exposure level of about 200 µg/day[3].

It is important to note that essentially all of the data collected on migration rates from cadmium-containing products to date have been based on products with very high cadmium concentrations that are not representative of typical children's jewelry products, leading to unrealistic cadmium migration concentrations. Data associated with more typical cadmium jewelry content values are limited, because migratable levels are reported near or below the detection limit. With regard to the CPSC data, the only jewelry product tested at a concentration below 2,000 ppm (sample number 10-302-2206 Key) had a reportable cadmium migration concentration of 0.4 µg, which is nearly 500 times lower than the CPSC recommended maximum allowable acute exposure level of about 200 µg/day. Based on data collected to date, total cadmium content concentrations in the range of 2,000 ppm to 6,000 ppm are not likely to result in harmful migration levels. In particular, even using a worse-case percent migration based on an unplated product, a total cadmium content of 2,000 ppm in a 3-

gram jewelry component is not expected to result in migratable concentrations that would pose an acute health risk if accidently swallowed.

Conclusions

The Fashion Jewelry & Accessories Trade Association (FJATA) commissioned testing of various metal jewelry samples (heart, winged circle, and cone shaped) to evaluate the relationship between total content of cadmium in jewelry and the migratable concentration. Higher total cadmium content concentrations (1%, 5%, and 10%) than what is representative of children's jewelry products were used in the testing program, to ensure accurate cadmium analytical quantification. Total cadmium content was measured, along with migratable cadmium using EN-71, 6-hour, 24-hour static, and 24-hour agitated testing methods. The results of the testing can be used to predict a total content concentration that is not expected to result in migratable concentrations that are likely to pose an acute health risk if accidently swallowed. Two different methods were used to evaluate this relationship.

Linear extrapolation from FJATA sampled jewelry

The FJATA testing data supported the use of a linear model to predict 24-hour agitated cadmium results for lower total content cadmium concentrations. With regard to the plated heart or winged circle jewelry samples, the evaluation indicates that the predicted 24-hour leachable cadmium levels for a 6000-ppm total content component ranges from 59.7 µg to 85.4 µg. For the plated wafer component, the linear model predicts a 24-hour leachable cadmium level of 49.7 µg for a 6000-ppm total content concentration. In all instances, these predicted cadmium concentrations are well below the CPSC recommended maximum allowable acute exposure level of about 200 µg/day.

Pooled estimates of cadmium migration

Although it is expected that the relationship between total content and migratable elements will differ based on such considerations as surface area and alloy composition, a general range of total to migratable cadmium can be determined based on the nearly 40 samples analyzed by both FJATA and CPSC Staff. The available data suggest that percent migration for plated products, even under aggressive conditions (24-hour agitated) is typically less than 0.5%. Recent data obtained from CPSC also confirm a low average percent migration of 0.38% when tested over a 24-hour period.

By applying a reasonable assumption of the percentage of material that will be released based on the total mass of a product and the total cadmium content, the total migratable cadmium can be predicted mathematically. Based on the combined FJATA and CPSC data collected to date, and using a representative 3-gram product, a total cadmium content of 2,000 ppm is not expected to result in migratable concentrations that are likely to pose an acute health risk if accidently swallowed.

The use of aggressive agitation and aeration in the 24-hour test method likely yields cadmium migration concentrations that are not good indicators of what may actually occur in the environment of concern—the stomach. Therefore, use of the 24-agitatation sampling method

likely yields an overly conservative migratable concentration to be used as a comparison to any toxicology criteria and provides a health-conservative interpretation of the data.

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374

Tables

374

375

Table 1: FJATA Cadmium Testing Results

Component Analyzed by FJATA	Cadmium Test Type	Base Metal	Content ppm	EN-71-3		6-hour				24-hour static				24-agitated			
				extracted mg/kg	dissolved %	extracted ug	mass gram	ug/g ppm	dissolved %	extracted ug	mass gram	ug/g ppm	dissolved %	total extracted ug	sample mass gram	ug/g ppm	dissolved %
Economy Plated	1% Cd heart	Tin	10,100											56	2.2189	25.2	0.25%
Quality Plated	1% Cd heart	Tin	10,100	< 1		< 1	2.2143			4.5	2.2599	2.0	0.02%	54	2.178	24.8	0.25%
Economy Plated	5% Cd heart	Tin	48,800											430	2.1892	196.4	0.40%
Quality Plated	5% Cd heart	Tin	48,800	2.37	0.0049%	18.6	2.2233	8.4	0.02%	116	2.2104	52.5	0.11%	527	1.9211	274.3	0.56%
Economy Plated	10% Cd heart	Tin	90,600											1520	2.2051	689.3	0.76%
Quality Plated	10% Cd heart	Tin	90,600	1.47	0.0016%	60.40	2.2991	26.3	0.03%	509.00	2.2383	227.4	0.25%	966	2.2371	431.8	0.48%
Economy Plated	1% Cd winged circle	Tin	12,400	< 1		6.1	4.5921	1.3	0.01%	28.1	4.3817	6.4	0.05%	116	4.44065	26.1	0.21%
Economy Plated	5% Cd winged circle	Tin	45,800	1.38	0.0030%	120.9	4.3034	28.1	0.06%	127	4.5075	28.2	0.06%	622	4.2167	147.5	0.32%
Quality Plated	5% Cd winged circle	Tin	45,800											852	4.2994	198.2	0.43%
Economy Plated	10% Cd winged circle	Tin	92,100	9.13	0.01%	186.40	4.5161	41.3	0.04%	763.00	4.2911	177.8	0.19%	1953	4.4002	443.8	0.48%
Quality Plated	10% Cd winged circle	Tin	92,100											2763	4.4385	622.5	0.68%
Avg %				**Avg.**	**0.005%**			**Avg.**	**0.03%**			**Avg.**	**0.11%**			**Avg.**	**0.44%**
Raw	1% Cd wafer	Tin	15,100	20.8	0.14%	195.2	3.0577	63.8	0.42%	287	2.7463	104.5	0.69%				
Raw	5% Cd wafer	Tin	50,100	136	0.27%	3901	3.078	1267.4	2.53%	1672	3.0318	551.5	1.10%				
Raw	10% Cd wafer	Tin	92,600	142.00	0.15%	4,879.00	2.91	1678.4	1.81%	1800.00	2.66	676.1	0.73%				
Avg %								**Avg.**	**1.59%**			**Avg.**	**0.84%**				
Economy Plated	1% Cd wafer	Tin	15,100											1572	33.7158	46.6	0.31%
Quality Plated	1% Cd wafer	Tin	15,100											313	33.3200	9.4	0.06%
Economy Plated	5% Cd wafer	Tin	50,100											6813	33.3200	204.5	0.41%
Quality Plated	5% Cd wafer	Tin	50,100											7755	33.6128	230.7	0.46%
Economy Plated	10% Cd wafer	Tin	92,600											11,196	28.9317	387.0	0.42%
Quality Plated	10% Cd wafer	Tin	92,600											19,296	33.9253	568.8	0.61%
Avg %																**Avg.**	**0.38%**
Raw	1% Cd cone	Zinc	12,700	<1		16	3.5473	4.5	0.04%	7.86	2.2829	3.4	0.03%				
Economy Plated	1% Cd cone	Zinc	14,100	<1		<1	6.8307			1.28	6.2661	0.2	0.001%				
Quality Plated	1% Cd cone	Zinc	11,500	<1		<1	7.0875			<1	7.1478						

375

376

Table 2: CPSC cadmium testing results [1]

Component analyzed by CPSC	Content		Migrated into 0.07 N HCl 24 hour				Migrated inot 0.9% NaCL, 6 hour			
			total extracted	sample mass	ug/g	dissolved	total extracted	sample mass	ug/g	dissolved
	ppm	%	ug	gram	ppm	%	ug	gram	ppm	%
08-810-5399 Ball	221,000	22.1	1.6	1.9	0.84	0.0004%	–	–	–	–
08-810-5399 Big Tree	239,000	23.9	18.3	2.54	7.2	0.003%	–	–	–	–
08-810-5399 Tree	301,000	30.1	1.1	1.3	0.85	0.0003%	–	–	–	–
08-810-5399 Hat	275,000	27.5	9.6	3.16	3.04	0.001%	–	–	–	–
08-810-5399 Stocking	295,000	29.5	8.0	1.96	4.08	0.001%	–	–	–	–
08-840-7306 charm	360,000	36.0	268.1	3.2180	83.3	0.023%	53.74	3.2180	16.7	0.005%
08-840-7306 charm	360,000	36.0	110.2	0.52	212	0.059%	8.06	0.52	15.5	0.004%
08-40-7306 charm	360,000	36.0	113.9	2.078	54.8	0.015%	–	–	–	–
10-302-2023 clasp	59,800	5.98	422.7	0.4278	988	1.652%	194.65	0.4278	455	0.761%
10-302-2023 Flake	982,000	98.2	176.5	1.6041	110	0.011%	365.73	1.6041	228.0	0.023%
10-302-2023 Man	991,000	99.1	7,002.8	2.78	2519	0.254%	60.05	2.78	21.6	0.002%
10-302-2024 Clasp	64,700	6.5	594.6	0.3912	1520	2.349%	167.82	0.3912	429	0.663%
10-302-2024 Tree	853,000	85.3	3,103.3	2.2586	1374	0.161%	215.24	2.2586	95.3	0.011%
10-302-2024 Cane	961,000	96.1	827.3	1.0702	773	0.080%	43.45	1.0702	40.6	0.004%
10-302-2024 Deer	993,000	99.3	27,064.0	1.9801	13668	1.376%	267.31	1.9801	135	0.014%
10-302-2206 heart	899,000	89.9	16,400.2	1.6055	10215	1.136%	794.72	1.6055	495	0.055%
10-302-2206 Key	285	0.0285	0.4	0.3381	1.21	0.425%	0.23	0.3381	0.67	0.235%
10-304-3090 Flower	190,000	19.0	6.3	8.7918	0.72	0.000%	0.70	8.7918	0.08	0.00004%
10-304-3415 Metal	755,000	75.5	2,942.0	0.308	9552	1.265%	37.58	0.308	122	0.016%
10-304-3415 Star	303,000	30.3	35.0	0.8568	40.80	0.013%	0.75	0.8568	0.88	0.0003%
10-304-3416 Star	307,000	30.7	116.3	0.8306	140.00	0.046%	0.29	0.8306	0.35	0.0001%
10-304-3417 Heart	361,000	36.1	20.0	0.9251	21.60	0.006%	4.84	0.9251	5.23	0.001%
10-304-3417 U	297,000	29.7	322.5	3.1313	103.00	0.035%	2.00	3.1313	0.64	0.0002%
10-304-3418 heart	377,000	37.7	4.0	1.0652	3.76	0.001%	4.15	1.0652	3.9	0.001%
10-304-3418 Crown	302,000	30.2	79.9	3.5195	22.70	0.008%	–	–	–	–
10-304-3419 Bracelet	878,000	87.8	59,828.6	3.09	19362	2.205%	–	3.09	169	0.019%
10-304-3420 Bracelet	900,000	90.0	10,677.5	3.012	3545	0.394%	–	3.012	142	0.016%
10-304-3421 Bracelet	899,000	89.9	25,815.7	3.035	8506	0.946%	–	3.035	143	0.016%
10-304-3422 Bracelet	899,000	89.9	9,733.9	3.236	3008	0.335%	–	3.236	108	0.012%
10-810-5600 Tag	298,000	29.8	12.3	0.748	16	0.006%	–	–	–	–
10-810-5600 Pendant	299,000	29.9	2,183.1	3.007	726	0.243%	–	–	–	–
10-810-5600 Clamp	260,000	26.0	5.1	0.415	12	0.005%	–	–	–	–
10-810-5601 Tag	272,000	27.2	35.1	0.769	46	0.017%	–	–	–	–
10-810-5601 Pendant	260,000	26.0	99.4	2.722	37	0.014%	–	–	–	–
Avg. %					**Avg.**	**0.38%**			**Avg.**	**0.08%**

[1] CPSC Memorandum. To Kristina Hatelid from Ian Elder. Assessment of Cadmium Migration from Materials. June 3, 2010

376

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Photographs

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From: Jack, Maia
To: Williams, John (ECY); Williams, John (ECY);
cc: Phillips, Keith (GOV); Terwilleger, Karen (ECY);
Kraege, Carol P. (ECY);
Subject: GMA Comments on Proposed Rule for WA"s Children"s Safe Product Act
Date: Friday, December 31, 2010 5:46:39 AM
Attachments: 20101231_GMA FINAL Comments to WA CSPA.pdf

Dear Mr. Williams:

Please find attached comments from the Grocery Manufacturers Association (GMA) regarding Washington's Proposed Rule for the Children's Safe Product Act of 2008. Thank you for your consideration.

Maia M. Jack, Ph.D.

Senior Manager, Science Policy - Chemical Safety

Grocery Manufacturers Association

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December 31, 2010

John R. Williams
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W2R HQ
PO Box 47775
Olympia, WA 98540-7775

submitted via email: john.williams@ecy.wa.gov

Re: Comments on Draft Reporting Rule for Children's Safe Products Act of 2008 - WAC 173-334 Rule Making

Dear Mr. Williams:

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of consumer packaged goods through scientific excellence. The GMA Board of Directors is comprised of chief executive officers from the Association's member companies. The $2.1 trillion consumer packaged goods industry employs 14 million workers and contributes over $1 trillion in added value to the nation's economy.

GMA appreciates the opportunity to participate in the development of Washington's Children's Safe Products Act of 2008 (CSPA) and submits this letter in response to Washington's Department of Ecology's (DoE) draft rule, "Chapter 173-334 WAC Children's Safe Products – Reporting Rule (October 22, 2010)[1]". This is a follow-up to GMA's August 13, 2010 comments on the Pilot Rule.

GMA comments in the letter address the following:

(1) Clarification on the scope of children's products, foods to be excluded;
(2) Appropriate trigger levels for Chemicals of High Concern to Children (CHCC);
(3) Suggested revisions to the draft regulatory text to include the concepts of "intentionally-added" AND "reliable";
(4) Some key issues in the risk-based prioritization process employed by the Department to identify CHCC;
(5) Specific chemicals that do not satisfy the criteria to be listed as a CHCC.

[1] http://www.ecy.wa.gov/laws-rules/wac173334/p0904a.pdf

(1) **Scope of Children's Products**

GMA is seeking clear and formal clarification in the rule regarding the scope of Children's Products[2] in the final regulation. It is GMA's understanding that the intent of the statute and of these regulations was and is to exempt food products and drug products. This is based on the Governor's partial veto letter[3] to CSPA, and correspondence with the Department of Ecology indicating that "foods" as defined within the Federal Food, Drug, and Cosmetic Act (FFDCA)[4] and as regulated by the United States Food and Drug Administration (FDA) were not within the scope of this rule. (*personal communication with Mr. John Williams in the Department of Ecology*, November 19, 2010).

In GMA's view, "A product designed or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by children" excludes foods to be eaten. However, we propose that the definition be made explicitly clear. GMA therefore recommends that the following definition be included under WAC 173-334-040 paralleling the same format as was done for children's cosmetics[2] under RCW 70.240.010 - Definitions (4):

> "A product designed or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by children " includes articles that are considered to be sleeping aids or feeding aids or reusable containers designed or intended primarily to be filled with a liquid or beverage for consumption from the container (e.g., sippy cups, baby bottles) or children's clothing. "A product designed or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by children " does not include soap, dietary supplements, or food and drugs regulated by the United States Food and Drug administration or by the United States Department of Agriculture.

It is GMA's view that foods[5] and drugs[6] should be expressly excluded from the scope of the above products subject to regulation under WAC 173-334-040, on the grounds that foods and drugs are covered under FFDCA and have a robust and comprehensive federal regulatory scheme administered by the FDA.

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[2] Per the statute, Children's Products include: (i) Toys; (ii) Children's cosmetics; (iii) Children's jewelry; (iv) A product designed or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by children; or (v) Child car seats. Under the "Definitions 3(b)" section (RCW 70.240.010), children's products not covered by the statute are listed. (http://apps.leg.wa.gov/RCW/default.aspx?cite=70.240.010)

[3] http://www.ecy.wa.gov/programs/swfa/cspa/pdf/2647Veto.pdf

[4] Federal Food, Drug, and Cosmetic Act (FFDCA) Section 201 (§ 201 (f), (g), (h), and (s)) (http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChaptersIandIIShortTitleandDefinitions/ucm086297.htm)(http://www.ajcn.org/content/71/6/1735S.full.pdf)

[5] http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/default.htm

[6] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

(2) Trigger Levels

GMA is very concerned about the trigger level reporting ranges specified in the Draft Rule[1]. DoE's "Phase 3 Report"[7] states, *" Concentration of chemicals of concern present at 0.1% in product components (1000 ppm) is a commonly accepted value, used by jurisdictions such as the European Union, to indicate that a chemical is intentionally added to a product… As a result, Ecology chose not to accept the recommendations of DOH/PEHSU with regard to individual reporting trigger levels for each chemical. Instead,* ***Ecology chose to bracket reporting ranges around the commonly used value of 0.1% (1000 ppm)*** *and the lower values recommended by the DOH and PEHSU for some chemicals."(emphasis added)* However, the draft seems to suggest reporting required for every chemical at concentrations above 40 ppm. There is no appropriate public health protection rationale for such a uniform and onerous requirement, and no explanation or justification for why the Department moved away from its position as stated in its Phase 3 Report. GMA suggests the rule clarify that reporting is mandatory ONLY WHEN intentionally-added CHCC are present at levels above a 0.1% (w/w) *de minimis* threshold, unless otherwise specified by the Department for certain CHCC with an appropriate lower trigger level supported by science-based evidence.

As noted in the Phase 3 report, there are existing resources in other regulatory systems that Washington could use as guidance in developing a system protective of public health, including endpoint-specific cutoff values articulated in the Global GHS guidance materials (which explicitly discuss adjusting thresholds) or those used by other countries in their GHS-based classification and labeling programs. For instance, under the EU's GHS Classification and Labeling program the *de minimis* trigger level is 0.1% (w/w) (i.e., 1000 ppm) in a product unless a different level is identified based on a health risk assessment (http://ecb.jrc.ec.europa.eu/classification-labelling/). The EU Cosmetic Directive contains specific threshold levels for over 300 chemicals that range between 0.001% and 25% (w/w) (http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/index_en.htm). In Proposition 65, California has developed chemical specific exposure limits. No Significant Risk exposure limits require consideration of how, regardless of the presence or total content of a substance in a consumer product, exposure to the environment and to users may occur. Washington should follow a harmonized pathway in implementing this reporting system to help maintain consistency throughout the regulating and regulated communities.

Consistent with the Phase 3 report[7], GMA recommends the use of 0.1% (w/w) (i.e., 1,000 ppm) as a default reporting trigger, adjusted if appropriate to apply health-based, chemical specific trigger levels based on the specific hazard levels in the listed chemicals. GMA strongly encourages the Department to return to its position in the Phase 3 report.

(3) Suggested Revisions to draft CSPA Reporting Rule

(3)(a) Intentionally-Added

GMA understands that the Department intended to focus the rules on those CHCC that are "intentionally-added" to children's products, per their Phase 3 report[7]. Specifically, DoE states, "***Ecology*** evaluated this recommendation and ***determined*** that for practical reasons, ***the focus should be on those chemicals that are intentionally added to children's products***." (emphasis added) Additionally, the Act[8] implies that its application is to intentionally added chemicals only,

[7] http://www.ecy.wa.gov/programs/swfa/rules/pdf/p3text.pdf
[8] http://apps.leg.wa.gov/RCW/default.aspx?cite=70.240.040

since it calls for chemical information such as CAS number, description of the chemical's function in the product, the amount used, etc. This means that only intentionally added chemicals should be covered by the reporting requirements. However, there is no definition or concept of "intentionally added" in the draft Rule.

GMA recommends the following language be included in the final rule –

Under the Definitions section WAC 173-334-040 in the draft rule[1], a proposed definition for "intentionally-added" ingredients might be:

> Intentionally-added. "Intentionally-added" in reference to a CHCC means a chemical that was added during the manufacture of the product or product component in the formulation or assembly of a consumer product where its continued presence is desired in the final consumer product to provide a specific characteristic, appearance, or quality or to perform a specific function, that serves a purpose at or above a 0.1% (w/w) *de minimis* threshold. (This threshold is consistent with other state, federal and international systems by which manufacturers are currently regulated.)

Under WAC 173-334-090 (1) of the draft rule, revisions to the text might include:

> "The notice required by RCW 70.240.040 must be filed annually with the department for each **INTENTIONALLY-ADDED** CHCC by-product category and component."

Under WAC 173-334-090 (2)(b) of the draft rule, revisions to the text might include:

> "The specific name and address of the facility which is responsible for the introduction of a**N INTENTIONALLY-ADDED** CHCC into a children's product or product component."

(3)(b) Reliable information

GMA believes that the term "reliable" ought to be included when "credible scientific peer-reviewed literature" is referenced under sections WAC 173-334-070 (4)(c) AND WAC 173-334-080 (1) and (2) of the draft rule[1]. Proposed alternate language would be: "credible **AND RELIABLE** scientific peer-reviewed literature."

Reliable information would be considered the test for acceptability to ensure that studies used are of appropriate quality, relevance (to human health and the environment) and adequate. The term "reliable" is recognized and used by the Organization for Economic Cooperation and Development (OECD) for "rating" studies in order to assure studies are both applicable and credible. We recommend this definition be placed under WAC 173-334-040:

> "Reliable". Reliable information is from studies or data generated according to valid accepted testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity

relationship ("QSAR") approaches validated in keeping with OECD principles of validation for regulatory purposes may be considered. The methodology used by the Organization for Economic Cooperation and Development (OECD) in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, July 2007) shall be used for the determination of reliable studies. (http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html)

(4) Risk-Based Prioritization Process

GMA believes that any state agency should focus its limited resources on the chemicals and exposures of greatest impact to human health. This can be accomplished by assuring that key criteria are established to identify, prioritize, assess, and manage high priority chemicals. A prioritization of chemicals must be done in a way that focuses on those substances that are of greatest, known concern to human health and the environment. Generally, we support:

- Risk-based prioritization to identify chemicals of highest concern through exposure, use, and hazard data relevant to the U.S. population; and
- A "weight-of-evidence" approach to chemicals prioritization that evaluates authoritative and reliable information on hazard traits, and considers the most severe hazards first.

GMA's specific comments in the Attachment discuss these key issues and specific recommendations in the context of the mandates of this statute and provide specific input on the data sources and approach used in populating the Chemical of High Concern to Children (CHCC) list.

(5) Specific Chemicals

Based on our concerns about the chemical selection criteria, process, and sources noted above, GMA believes that the following chemicals have been improperly included in the Draft CHCC List and respectfully requests their removal from the reporting program. The fact that these substances appear on the proposed CHCC list suggests the need for a more robust categorization process than the one developed to date. The designation of a chemical as a CHCC should be grounded in both scientific and practical terms and not simply by an algorithm.

- Butyl, ethyl, methyl and propyl paraben and 4-hydroxybenzoic acid. These are well recognized and invaluable ingredients approved for use in pharmaceuticals, food, and cosmetics by FDA and European regulators to prevent health risks from microbiological contamination. Further, both methyl and propyl paraben are Generally Recognized as Safe (GRAS), evaluated by the Select Committee on GRAS Substances as category 1, which is defined as meeting the following: "There is no evidence in the available information on [the substance] that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or might reasonably be expected in the future." These chemicals were listed based on the EU Endocrine Disruption list, an inappropriate source. (please see Attachment for further details)

- Bisphenol A (BPA). This chemical should be excluded from the list on the following basis - the Dev. & Repro. determination should, under the Department's ranking system, be downgraded to "Bad". First, BPA was reviewed in 2010 by the Prop 65 DARTIC and

they declined to list it. Second, as described in the Attachment, the WA DoE's approach to ranking NTP's Center for Evaluation of Risk to Human Reproduction (CERHR) findings should follow the actual classification used by the authoritative body, as it did in the case of every other source. To be consistent, CERHR's rankings should be applied directly as are all rankings from all other sources. The logical approach, following rankings for other systems, would be that the determination for the substance would be downgraded to "Bad". Lastly, as described above, the EU Endocrine Disruption information should not be used in any circumstances.

* * * * *

GMA is committed to assisting the Department in developing a credible and workable Green Chemistry program that will not only achieve the Green Chemistry Initiative's objectives, but also be a model for the U.S. If you have any questions or comments, please feel free to contact us. We look forward to our continued work together on this important public policy initiative.

Sincerely,

John Hewitt
Director, State Affairs
Grocery Manufacturers Association
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Sacramento, CA 95814
916-508-6278
JHewitt@gmaonline.org

cc: Keith Phillips, Office of Financial Management
Karen Terwilleger, Department of Ecology
Carol Kraege, Department of Ecology

Attachment

Prioritization Criteria and Sources

Washington's Department of Ecology has taken an in depth approach to scanning the globe for hazard and exposure information and a series of steps in coming to decisions about primary versus secondary sources to determine priorities and a phase 2 ranking approach to select chemicals for reporting. In some areas, the choices seem to be reasonable; however, there remain significant concerns with the process employed and GMA requests that chemical selection be updated to reflect the following changes and suggestions. In brief, 1) only chemicals presenting known hazards should be listed, 2) the listing must be from an authoritative source, and 3) sources that are not transparent and publicly available should not be relied upon. The Department must assess each chemical and the source of the listing to confirm that these criteria are met.

HAZARD SOURCES

GMA concerns with sources used during priority setting are as follows:

- **"Known" Hazards.** The legislation focuses attention on high priority chemicals that "...on the basis of credible scientific evidence as **known** to do one or more of the following..."[9]. In toxicology, "known" is the most stringent standard for knowledge about a chemical's toxicological properties, and indicates that the weight of the evidence evaluation of the available data and information supports the determination. "Known" means that there has been an expert judgment made based on appropriate, quality scientific information. It does not mean that the evidence *suggested,* or that a hazard is *suspected, potential*, or *possible*. The known criterion should be used to appropriately narrow the focus to the very highest hazard priorities, i.e., a known carcinogen, a known reproductive toxicant. Moreover, the listing of chemicals with "known" hazards should be specific in terms of route of potential exposure. DoE did not adhere to this "known" hazard criterion in its chemical selections.
- **Hazard Severity**. There does not seem to be a transparent set of criteria for consideration of "severity"—e.g., that chemicals which have multiple hazards or have been reviewed and classified by more than one authority should receive higher priority. Nor is there a consideration of the severity of the type of toxicity—carcinogens and reproductive toxicants whose effects are seen from chronic, repeated exposures at relatively low doses would clearly be more severe than chemicals having one-time (acute) or subchronic effects that are seen at relatively high doses or are reversible.
- **Inappropriate Hazard Information Sources.** Washington should only be selecting chemicals posing a known hazard from source information that is authoritative in nature. Authoritative would be a government agency or formalized scientific organization that: (1) characterizes chemicals pursuant to an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments; (2) is widely perceived to be objective, scientifically based, and does not engage in advocacy; (3) bases its characterization of chemicals on a weight-of-evidence approach; (4) publishes its characterizations of chemicals through governmental

[9] "High priority chemical" means a chemical identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative by the department on the basis of credible scientific evidence as **known** to do one or more of the following…" (http://apps.leg.wa.gov/RCW/default.aspx?cite=70.240.010)

regulations, periodic reports, monographs or similar publications. The Department of Ecology has drawn from a very large and heterogeneous global set of source lists. Many chemical selections are inappropriate either because the source was not authoritative in nature or because chemicals were selected from sections of authoritative lists that go beyond the "known" standard in the statute. Specific concerns include:

- Proposition 65 developmental/reproductive. Because there are different routes by which a chemical may be listed under Prop 65, the basis for the listing – and not just that fact that a chemical is listed - must be considered. Prop 65 is an authoritative source for those chemicals that are listed per the recommendation of the CA Developmental and Reproductive Toxicant Identification Committee (DARTIC). Prop 65 may be an authoritative source for chemicals that are listed based on certain "authoritative bodies," e.g., NTP CERHR. However, certain other bodies considered "authoritative" for purposes of Prop 65 listing purposes are inappropriate for consideration by the Department under the CSPA (e.g., some occupational hazards listed in the CA Labor Code).
- NTP CERHR finding. This is an authoritative source. However, unlike the approach used for every other source, the Department did not use the actual CERHR classifications in developing the CSPA chemical determinations, but rather an alternate approach. To be consistent and transparent, CERHR's classifications should be applied directly, as are every other ranking of chemicals from every other source. The logical approach, following rankings used from other sources would be: Worst—Serious Concern; Severe—Concern; Bad—Some concern.
- EU Existing Substances (Reproductive/Developmental). This is an authoritative source, however some chemicals selected ranked Category 1A and 2 were designated *Presumed* and *Suspected* by the EU (not "known"). The analysis also does not seem to acknowledge EU classification Category changes made in January 2010 (Category 1A, 1B and 2, instead of the previous Category 1, 2, 3.
- Japan GHS Reproductive/Developmental. This is an authoritative source, however some chemicals selected ranked Category 1B were in fact designated *Presumed* by Japan GHS (not "known").
- REPROTEXT. This is not a public database, and is not searchable to confirm the information included or the criteria used. For transparency purposes, it should not be a source for any decisions in CSPA, a program that itself is aimed at increasing transparency of chemicals contained in consumer products.
- LOAEL or RTECS. This category is puzzling and not well explained in the Phase 2 report. It appears from the hyperlinks that it is aware of information in ATSDR and/or from Canada's Occupational Health and Safety databases, but was the information from ATSDR or RTECS used at all in making selection decisions? Like REPROTEXT, Canada's database is not open to the general public or searchable to confirm the information included or the criteria used, so it should not be a source of decisions in a program that is about transparency. The other major concern is the set of values indicated in the Worst/Severe/Bad rankings. What is this source of these values? Are they supposed to be the values for acute toxicity from the GHS system? Values for repeat dose toxicity from GHS? Without clear and transparent decision logic and data sources backing up this part of the determination process, this section of the evaluation should be removed.

- EU Endocrine Disruptors. This is not a reliable source for CSPA and should not be used in any respect. This list was developed in 1999 by a consultant, BKH. That list never was the subject of any kind of deliberative scientific review or decision-making by EU Authorities and there was no input by stakeholders. It does not represent any level of scientific consensus. In fact, a review by the EU's Science Advisors (CSTEE) did "not find the source material, methodology and selection criteria used to be scientifically adequate" and concluded "that there are important shortcomings in the present approach". (EU Scientific Committee on Toxicity, Ecotoxicity and the Environment, Opinion on BKH Consulting Engineers Report http://ec.europa.eu/health/ph_risk/committees/sct/docshtml/sct_out73_en.print.htm. There have been no changes or updates to the BKH work since the CSTEE review, nor any EU regulatory activity based on it. It has no place as a source in CSPA.
- IARC. This is an authoritative source, however some chemicals selected are from Group 2a Carcinogens (not "known").
- National Toxicology's Program (NTP) Carcinogens. This is an authoritative source, however some chemicals were selected that NTP had classified *Anticipated* (not "known").
- EPA IRIS. This is an authoritative source, however some chemicals selected ranked Category B1, B2 or Likely (not "known").
- EU Carcinogens. This is an authoritative source, however some chemicals selected ranked Category 1A and 2 were classified as *Presumed* or *Suspected* by the EU (not "known"). The analysis also does not seem to acknowledge EU classification Category changes made in January 2010 (Category 1A, 1B and 2, instead of the previous Category 1, 2, 3.
- Japan GHS Carcinogens. This is an authoritative source, however some chemicals selected ranked Category 1B are categorized by Japan GHS as *Presumed* (not "known").
- Proposition 65 Carcinogens. This is in part an authoritative source. Because there are different routes by which a chemical may be listed under Prop 65, the basis for the listing – and not just that fact that a chemical is listed - must be considered. Prop 65 is an authoritative source for those chemicals that are listed per the recommendation of the CA Carcinogen Identification Committee, however, certain other bodies considered "authoritative" for purposes of Prop 65 listing purposes are inappropriate for consideration by WA under CSPA (e.g., some occupational hazards listed in the CA Labor Code).

EXPOSURE SOURCES

- A major concern in this part of the prioritization is the dependence on non-US information (Danish, Dutch, EU) about product uses and exposures and the weight assigned to those sources versus US EPA, FDA and NLM databases. The EU Risk Assessment work is a very old source (e.g. 15+ years). It should not be used for CSPA except in the case of chemicals where regulatory actions were taken to reduce children's exposures following completion of the risk assessment. In addition, the use of an environmental advocacy group's database (EWG) has no place in a deliberative state scientific process for identifying priorities.

- EPA's Voluntary Children's Chemical Evaluation Program. This was a list developed by EPA about 10 years ago and led to the development of risk assessments for each of the chemicals. The development of the list did not include any direct information on Children's exposure and should be excluded from this chemical selection process, unless the VCCEP chemical assessments themselves document exposures of concern to Children.

APPROPRIATE SOURCES FOR IDENTIFYING KNOWN HAZARDS

The following offers a recommendation for WA DoE on clear criteria and on a set of global Authoritative Body source lists to support identification of chemicals for CSPA. It would be appropriate for Washington to first focus on "known" Reproductive, Developmental toxicants and Carcinogens for the initial reporting.

Criteria

"Chemicals known to cause cancer in humans" means chemicals that have been classified in (i) the International Agency for Research on Cancer ("IARC") category 1 or (ii) an equivalent category in a similar classification system promulgated by another authoritative body such as US EPA, California Proposition 65 (subject to the caveat explained above), the National Toxicology Program Report on Carcinogens, or the European Union. "Chemicals known to cause reproductive harm" means chemicals that have been classified as known reproductive or developmental toxicants by an authoritative body such as US EPA, California Proposition 65(subject to the caveat explained above), the National Toxicology Program Center for Evaluation of Risks to Human Reproduction (CERHR), or the European Union.

Relevant Sources

- EPA Carcinogens. This has been collected since 1986 and the main challenge is that the ranking terminology has changed 4 or 5 times, most recently in 2005. Chemicals included should be those classified as Known or Category A. (http://www.epa.gov/opp00001/health/cancerfs.htm)
- NTP Report on Carcinogens. Chemicals included should be those classified as Known to Cause Cancer in Humans (http://ntp.niehs.nih.gov/?objectid=72016262-BDB7-CEBA-FA60E922B18C2540)
- Prop 65. Chemicals included should be Carcinogens and Repro/Developmental toxicants that were identified under Health and Safety Code section 25249.8(b) (http://www.oehha.ca.gov/prop65/policy_procedure/listde051007.html).
- IARC. Chemicals included should be those classified as Category 1. (http://monographs.iarc.fr/ENG/Classification/index.php)
- NTP CERHR. Chemicals included should be those identified as Serious Concern for reproductive/developmental toxicity. (http://cerhr.niehs.nih.gov/index.html)
- EU Classification. Chemicals included should be those previously classified as Category 1 under Annex I of Directive 67/548/EEC and now in transition to be classified as Category 1A under Annex VI, part 3 of Regulation (EC) 1272/2008. (http://ecb.jrc.ec.europa.eu/classification-labelling/)
- EU's Registration, Evaluation, Authorisation and Restriction of Chemicals' (REACH) Substance of Very High Concern (SVHC). SVHC is a list of substances in Annex XIV subject to authorization under Regulation (EC) No 1907/2006 of the European Parliament concerning REACH. Chemicals recommended as Candidates to be

Substances of Very High Concern in the EU's REACH Program which will include reproductive and developmental toxicants and carcinogens.

Chemicals identified from the hazard/exposure sources or portion of sources with noted concerns (i.e., on pp. 5, 6, and 7 under "Hazard Sources" and "Exposure Sources") should not be included in the CSPA. Eliminating the chemicals from these sources and relying on the "appropriate hazard/exposure sources", as noted above and under the "Exposure Source" section on p.7, will help to generate a more focused and proper list of Chemicals of High Concern with "known" hazards as envisioned in the Statute. Using these general criteria will help generate a more focused and applicable list of CHCC.

Endocrine Disruption

The CSPA statute includes chemicals known to cause disruption of the endocrine system as one of the criteria for chemical selection. As evidenced by the lack of any currently validated protocols to evaluate substances for their endocrine disruption potential, it is clear that this is a field of science that is in its relative infancy compared with other toxicology endpoints. In addition, the relationship of human diseases to the endocrine system is poorly understood and scientifically controversial. As described in the section above, the EU source list for these chemicals had no deliberative scientific review or decision-making by EU Authorities and no input by stakeholders. It does not represent any level of scientific consensus. The fact that a contemporaneous review by the EU's Science Advisors (CSTEE) determined that it did "not find the source material, methodology and selection criteria used to be scientifically adequate" and concluded "that there are important shortcomings in the present approach" makes clear that this is not a reliable source for CSPA decisions. Regulatory action, including reporting requirements under CSPA should not be based on individual studies or hypotheses that use un-validated methods, do not conform to comply with Good Laboratory Practices, and that otherwise fail to meet the basic expectations for adequate regulatory science.

The draft list includes 12 substances that are present solely due to their classification as potential endocrine disruptors. These 12 substances should be removed from the initial draft list until more reliable assessment techniques or consensus conclusions are available for evaluating endocrine disruption potential and its relationship to health outcomes. The Department should look to the results on validated protocols from EPA's Endocrine Disruptor Screening Program's (EDSP) Tier 2 Testing. The United States EPA is at the forefront of developing a testing program that can serve as the basis for chemical prioritization and potential risk management efforts. The EPA approach involves a Tier 1 battery of assays to detect for the potential of a substance to interact with the endocrine system. Depending on the results of Tier 1, a substance may to through a second battery of tests (Tier 2) that are designed to establish dose-response relationships for adverse effects. EDSP uses a Weight of Evidence approach to determine both the potential to interact with the endocrine system and whether any adverse outcomes have an endocrine-related mode of action.

Confidential Business Information

GMA is pleased to see that the draft rule contains provisions that will protect Confidential Business Information (CBI) from disclosure to competitors. This is a critically important aspect of this program. To ensure that submitted CBI is in fact protected from release, we encourage the Department to develop strong procedures so that submitters can be certain that their trade secret information will be adequately protected.

From: Erika Schreder
To: Williams, John (ECY);
Subject: my testimony
Date: Tuesday, December 21, 2010 9:35:32 AM
Attachments: testimony 12.9.10.doc
ATT2126785.htm

Hi John,

Would you mind forwarding this to the hearing officer? I realized later that what I handed her was an earlier draft.

thanks so much,

Erika

 393

Testimony of Erika Schreder
Staff Scientist, Washington Toxics Coalition

Thank you for this opportunity to provide testimony. My name is Erika Schreder and I am the staff scientist for the Washington Toxics Coalition. We would like to thank the Department of Ecology for moving forward with this important rule that will help fill critical data gaps on the use of harmful chemicals in toys and other children's products.

It is clear from ongoing reports that the use of toxic chemicals in children's products is still prevalent and many are not adequately regulated by federal law. This state action provides much needed information to both state and federal efforts to illuminate the problems we still face. Here are two examples:

- In the summer of 2010, over 10 million Shrek glasses from McDonald's were voluntarily recalled after carcinogenic cadmium was found. Following this recall, the federal government decided not to impose mandatory cadmium limits. They are voluntary.

- Recent studies have shown that certain baby shampoos can contain formaldehyde, 1,4-dioxane, and methylene chloride, all of which are listed on the high priority chemical list.

In addition to the critical information this rule will provide, we believe it will help manufacturers in their quest for safer products. We know many companies are trying to do the right thing and get information from suppliers on the toxic content of their products and this has been a challenge. With this new rule in place, more information will flow in the supply chain, creating more opportunity for better material or product choices. Again, we thank the agency for proceeding with this rule and for being a pioneer in policies that drive companies to safer chemicals.

We have specific comments on the rule related to the chemical list, reporting thresholds, getting more information on the extent to which chemicals are used, and ensuring wide public access to the information that is gathered.

Chemical List. Overall, we think that Ecology captured many chemicals that are of high concern for children. The methodology and scientific support for the inclusion of these chemicals are strong and we appreciated the process by which it was developed, including the review and work by the University of Washington. In particular, we appreciate the addition of cadmium to the list.

However, we have several concerns. First, lead and certain phthalates have been left off the list. Consumers continue to be concerned about these chemicals in children's products because the federal lead limits are quite high (300 ppm) and

 393

 394

only a few phthalates are prohibited. We do not believe that federal law pre-empts the agency from obtaining this information and we think these chemicals should be on the list.

Finally, the agency did not specifically include chemicals that are neurotoxic as required by law. We ask that these chemicals be prioritized when the agency updates the list in a future rulemaking.

2. The reporting threshold level.

Ecology has the right approach in this rule with respect to the reporting threshold level. The disclosure part of the law was not intended to establish safe levels of chemicals in products. It was designed to provide consumers and the government with more information about harmful chemicals in children's products.

But while the general approach is correct, we are concerned that the 40 ppm reporting trigger value is too high to capture certain harmful chemicals that are in children's products.

For example, according to previous studies that have been published, a 40 ppm miminum would miss formaldehyde in baby mittens, styrene and toluene in baby jackets, and N-nitrosodimethylamine in pacifiers and nipples. These are chemicals that Ecology has ranked as carcinogens, developmental and reproductive toxicants, but they are present in these products at levels below 40 ppm.

To capture these and other chemicals, we continue to believe that reporting should be based on level of detection. In other words, any amount above detection limits should be reported. In order to ensure that this is not too onerous for manufactures, we would consider language that makes it clear this applies only when chemicals are intentionally added, used in the manufacturing of the product, or are known process contaminants.

 394

 395

Setting the reporting requirements based on detection limits will ensure a clear requirement and not create questions of whether the level is too protective or not protective enough.

3. Requirements for disclosing numbers of products containing a given chemical.

The law was very clear that manufactures needed to provide the chemical data for each product unit. RCW 70.240.040(4) clearly states that the manufacturer must report, "The amount of the chemical used in each unit of the product or product component." The current rule draft does not ensure that information on each product that contains the chemical is obtained because it allows for reporting by product category. This may ease implementation, but we are concerned that a large data gap will persist: to what extent is the chemical used?

For example, if a manufacturer reported the specific chemicals contained in "Baby Doll X," we would be able to figure out how widespread the exposure may be based on the popularity of the particular product. But if we only know it is used in baby dolls, it doesn't tell us much about the extent of the chemical's use. If the agency isn't going to follow the letter of the law and require data on each product, then at a minimum, it should require manufactures to disclose how many product units (approximately) the chemical was used in. This will allow the Department of Health to provide more accurate information to consumers on the chemicals in products, which is also required by the law. And it will provide useful information to Ecology on what product categories should be prioritized for development of safer alternatives.

4. Public Access to the Information:

The intent of the law was to provide the information to the public via the web and specific language was in the bill that passed in the legislature. The rule states that manufactures have to use a web form when providing notification to the department. We would like the rule to also specifically state that Ecology will make this information publicly available on a website or at the very minimum we would like Ecology to come up with a plan for how this information will be published on the web and distributed to the public.

 395

From: Glen Cooney
To: Williams, John (ECY);
Subject: RE: CERC Comments - Children"s Safe Products Reporting Rule
Date: Friday, January 07, 2011 2:39:55 PM
Attachments: CERC WA state children"s safe products rule 12 20 10 Final.docx

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Mr. Williams:

On behalf of the Consumer Electronics Retailers Coalition (CERC), please accept these comments on the children's safe products reporting rule (Chapter 173-334 WAC).

Glen Cooney
e-Copernicus
317 Massachusetts Ave., NE
Suite 200
Washington, DC 20002
202.292.4600 (tel)
202.292.4605 (fax)

Consumer Electronics Retailers Coalition

CERC

www.ceretailers.org

January 7, 2011

John R. Williams, Jr.
Department of Ecology
PO Box 47600
Olympia, WA 98504-7600
Submitted via email: john.williams@ecy.wa.gov

RE: CERC Comments – Children's Safe Products Reporting Rule

Dear Mr. Williams:

CERC is a public policy organization consisting of the major retailers of consumer electronics products including Amazon.com, Best Buy, RadioShack, Sears, Target, Wal-Mart, and the leading industry trade associations – National Retail Federation (NRF) and Retail Industry Leaders Association (RILA). Our members are among America's favorite places to shop for electronics devices which make our lives more productive and enjoyable.

Our members have combined to focus our unique and expert market perspective on the critical policy issues facing the consumer electronic retail industry and our customers. Individually, our members operate in all 50 states and territories, collectively employing well over three million people nationwide.

CERC would like to respectfully submit the following comments with respect to the Department of Ecology's draft Children's Safe Products Reporting Rule (Chapter 173-334 WAC). As retailers (and in some cases private label manufactures) our goal is always to ensure that the wide array of products sold in our stores, on-line and in Washington are safe for our customers to use, a goal doubly important with children's products.

We do feel it worth noting that despite some common misperceptions, chemicals used in products are very often designed to benefit the consumer, such as increasing the resistance to heat and fire and ensuring plastics are not too brittle, which could lead to hazards for children.

As you know, in 2008 when Gov. Gregoire vetoed sections of HB 2647, she stated in her veto message that "…without careful implementation, this bill could adversely affect the availability of safe toys in our state, including important educational toys…" In addition, the Governor directed the Department of Ecology to "focus on the highest priority chemicals…and use those chemicals

likely to be found in children's products…"

CERC believes that the current draft rule is not only inconsistent with the Governor's direction to the Department but in fact needs to be amended to reflect the following:

1. The threshold of 40 ppm (.001%, or .00001) is far too low, and beyond the ability of modern testing equipment to accurately measure at that extremely low level. Instead, CERC supports adopting a standard consistent with the European Union of 1,000 ppm (.1%) which has been determined worldwide to be more than adequately protective of human health.

2. The reporting requirements should be limited to those chemicals that a manufacturer intentionally adds to a product. A product manufacturer should not be required to test for chemicals that are not part of the product manufacturing or design. In addition, domestic distributors should be exempt from these chemical reporting requirements as domestic distributors do not have access to such information.

3. The list of chemicals manufacturers are required to report needs trimming. As the Washington Department of Health and the University of Washington reported in July 2010, 27 of the chemicals on the Department of Ecology's list are not likely to be intentionally added to products. We believe those 27 chemicals should therefore be removed from the reporting requirements. Where federal standards have been established, the state will harmonize with the limits set in those federal standards.

4. The reporting rule should be limited to product components that a child is likely to contact. Internal parts and parts that are inaccessible and highly unlikely to come into contact with children through reasonable and foreseeable use should be exempted from the reporting obligations of the rule.

CERC appreciates the opportunity to comment on the Department of Ecology's reporting rule prior to its final adoption. We look forward to working constructively with the Department and the Governor in the future to ensure that that the final CSPA rule is protective of children and all consumers' health.

Sincerely,

Gregory Rohde
Executive Director
Consumer Electronics Retailers Coalition
317 Massachusetts Avenue, NE, Suite 300

Washington, DC 20002
(Tel.) 202.292.4600
glr@e-copernicus.com

From: Silk Road
To: Williams, John (ECY);
Subject: RE: Children"s safe product rule
Date: Tuesday, October 26, 2010 3:42:32 PM

Wow, that was fast, thanks.
While there is no re uirement for testing, there actually is, since the responsibility for reporting is on the first importer if I read this correctly, with penalties for non compliance. In essence, you would be forced to test to ensure compliance or risk the supplier, who may or may not use the correct procedure, to send you a compliance letter. If you have dealt with importing, this would be very difficult to obtain. My supplier had never seen or heard of a MSDS before dealing with our company.

Our company is looking at importing solar based toys, in fact, I was at the Canton trade show last month in China to check out possible suppliers, and you may actually see one or two in the building, we give out solar powered flowers as promo's , which could also be considered a children's toy.

Cheers
Ray

From: Williams, John (ECY) [mailto:jowi461@ECY.WA.GOV]
Sent: Tuesday, October 26, 2010 8:35 AM
To: Silk Road
Subject: RE: Children's safe product rule

Hello Mr. Lam

Please see responses below.

Thank-you
John

John R. Williams Jr.
Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

360/407-6940
FA 360/407-6102

owi461 ecy.wa.gov

Please consider the environment before printing this e-mail

From: Silk Road [mailto:gardener@silkroadenvironmental.com]
Sent: Monday, October 25, 2010 11:04 PM
To: Williams, John (ECY)
Subject: Children's safe product rule

I am wondering how the figure on the impact to small business has been calculated.
The small business impact statement and other rule making documents are on-line:
http://www.ecy.wa.gov/laws-rules/wac173334/0904.html
If these do not ade uately answer this uestion, I can put you in touch with the economist who wrote them.

If I want to import, say baby shoes, wouldn't I be obligated to test for each item on the list Also, would I not have to test each separate item, ie every color of the shoe separately
There is no re uirement to test at all in the law or the rule –

Also, the is an assumption, and I would assume incorrect, that the list is stagnant, but instead likely to grow, so unless you assume the list will not grow over the 20 years in the impact study, the cost of compliance seems well understated to me.
While the rule does state how a chemical can be added or removed from the list – any such modification would re uire a new rule, which would re uire a new economic impact statement.

I would also point out that the reporting re uirement is being phased–in. For some manufacturers and products this means that the first reports would not be due for 7 years from the date the rule is adopted. After looking at your web site I am unclear on how you feel this rule would impact your business.

Saving the planet one pound at a time.

Raymond Lam

President
Silk Road Environmental
A Solutions Company
Kennewick, WA 99337
(509) 460-3012
www.silkroadenvironmental.com
email:gardener silkroadenvironmental.com

From: Pam Utz
To: Williams, John (ECY);
cc: Kraege, Carol P. (ECY); Frazier, John; Ying, Helga; Goldman, Laurie; Man, Kitty; Nathaniel Sponsler; Ylva.Holmquist@hm.com; Mattias Bodin; Pidgeon, Elena; Elizabeth A. Treanor;
Subject: RE: Comments from Gap, H&M, LS&Co. and Nike
Date: Thursday, December 23, 2010 3:07:07 PM
Attachments: Dec Letter G-H-L-N WA State CSPA.pdf

Dear John,

After further reflecting on the uestion of the concentration limit for reporting chemicals of high concern, our four companies respectfully submit an additional comment on the Washington State Children's Safe Products Act (CPSA) Draft Regulations (173-334 WAC).

Should you have any uestions, please do not hesitate to contact one of us.

Best Wishes for the New Year

Pam Ut , Nate Sponsler – GAP, Inc.
Ylva Holm uist, Mattias Bodin – H&M
Kitty Man, Elena Pidgeon – LS&Co.
John Fra ier – Nike, Inc.

Pam Ut / Director Gap Inc. Product Regulations / 2 Folsom St. 6 fl / San Francisco, CA 94105 / 415-427-6972

December 22, 2010

TO: Mr. John R. Williams
Washington State Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600

RE: Children's Safe Product Act (CSPA) RCW 70.240, 173-334 WAC

Dear John,
The undersigned companies wish to reaffirm comments submitted October 1 on the Children's Safe Products Act (CPSA) Draft Regulations (173-334 WAC).

In the current, updated Draft Regulation, reporting ranges for chemicals of high concern for children (CHCC) in product components start at 40 ppm [WAC 173-334-090 (1)(e)(i)]. We previously requested that reporting ranges start at 0.1% (1000 ppm). It was noted that:

- Chemical manufacturers are not required to declare substances below 1000 ppm on Material Safety Data Sheets (MSDS).
- EU REACH reporting requirements for gathering information on Substances of Very High Concern (SVHC) start at 1000 ppm. Below this level chemicals are considered to be present at trace levels.

On November 15, California's Department of Toxic Substances Control provided its rationale for adopting a *de minimis* level of 1000 ppm for triggering alternative assessment requirements in the Rulemaking on Safer Consumer Product Alternatives[1]:

> "DTSC is also still convinced that 0.1% is the appropriate and necessary default value for a de minimis level cut-off. The 0.1% standard is not a universal value, but it is far and away the most commonly used level for various regulatory programs that, of necessity, recognize a level below which something is not subject to regulation."

Further investigation of the *de minimis* issue led us to the US Environmental Protection Agency (EPA) program on "Design for the Environment" (DfE). Under a voluntary partnership program with the cleaning products industry to reduce chemical risk in formulated products, EPA set the *de minimis* reporting level for known residuals at 100 ppm (0.01 percent)[2]. Residuals are "trace amounts of chemicals that are incidental to manufacturing."[3]

We agree that reporting chemicals above 100 ppm can make sense for *formulated* products, which are chemical mixtures based on recipes of known ingredients. However, it is not a realistic reporting level for *unformulated* products like apparel and apparel accessories (footwear, bags, jewelry, etc.). The

[1] "15-Day Public Notice and Comment Period – Notice of Public Availability of Post-Hearing Changes - Safer Consumer Product Alternatives," R-2010-05, p.6
http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA_15Day_Notice_11162010.pdf
[2]See "DfE Standard for Safer Cleaning Products (SSCP),"Revised March 2010 section 3.2.1
http://www.epa.gov/dfe/pubs/projects/gfcp/standard_for_safer_cleaning_products.pdf

[3] Definition 2.1.54, page 5.

latter are assembled from components provided by suppliers, sub-suppliers, and sub-sub-suppliers. Unformulated products consist of material substrates, including natural and synthetic, with many possible combinations of formulations like dyes, adhesives, finishes, and coatings. The complexity of unformulated products makes it difficult for those at the end of the manufacturing chain to track precise chemical concentrations of residuals in their products. This complexity is a major reason why leaders in our (and other) industries rely on chemical hazard, coupled with an evaluation of the potential for materials to contain chemicals, as the basis for Restricted Substances Lists (RSLs). We believe this prescriptive approach allows for meaningful engagement of our supply chain and greater protection of the consumer.

We continue to believe 1000 ppm is the reporting floor that best supports Washington's objectives to obtain reliable information, cost effectively, on chemicals in a diverse range of children's products (both formulated and unformulated). If Washington believes it is necessary to require reporting below 1000 ppm, we strongly recommend that the reporting levels be based on scientific, toxicologically relevant values and be subject to public review and comment.

Thank you again for your time and attention on this matter. Please do not hesitate to contact us if you have any questions or need additional information.

Cordially yours,

Pam Utz, Director, Product Regulations, Gap Inc.
Nathaniel Sponsler, Project Manager, Product Regulations, Gap Inc.

Gap Inc.

Mattias Bodin, Quality Assurance Manager H&M
Ylva Holmquist, RSL Responsible H&M

H&M

Elena Pidgeon, Senior Manager, Product Safety LS Americas, Levi Strauss & Co.
Kitty Man, Ph.D., Global Leader, Restricted Substances, Levi Strauss & Co.

LEVI STRAUSS & CO.

John Frazier, Director of Sustainable Chemistry and Water, Sustainable Business and Innovation, Nike Inc.

About our companies

About Gap, Inc.
Gap Inc. is a leading global specialty retailer offering clothing, accessories, and personal care products for men, women, children, and babies under the Gap, Banana Republic, Old Navy, Piperlime, and Athleta brands. Gap Inc. operates about 3,100 stores in the United States, Canada, the United Kingdom, France, Ireland, and Japan.

About H&M
H & M Hennes & Mauritz AB (publ) was founded in Sweden in 1947 and is quoted on NASDAQ OMX Stockholm. The company's business concept is to offer fashion and quality at the best price. In addition to H&M, the group includes the brands COS, Monki, Weekday and Cheap Monday as well as H&M Home. The H&M Group has around 2,000 stores in 37 markets. In 2009, sales including VAT were SEK 118,697 million and the number of employees was around 76,000. For further information, visit www.hm.com.

About Levi Strauss & Co.
Levi Strauss &Co. is one of the world's largest brand-name apparel marketers with sales in more than 110 countries. There is no other company with a comparable global presence in the jeans and casual pants markets. Our market-leading apparel products are sold under the Levi's®, Dockers®, deniZEN™ and Signature by Levi Strauss & Co.™ brands. Based in San Francisco, California, LS&Co. is a global corporation with roughly 11,000 employees worldwide. For more information, visit www.levistrauss.com.

About NIKE, Inc.
NIKE, Inc. based near Beaverton, Oregon, is the world's leading designer, marketer and distributor of authentic athletic footwear, apparel, equipment and accessories for a wide variety of sports and fitness activities. For more information, visit www.nikebiz.com.

From: Kristin Power
To: Williams, John (ECY);
Subject: Rule Proposal Notice Chapter 173-334 WAC
Date: Wednesday, January 05, 2011 9:33:59 AM
Attachments: WA Children"s Safe Products Reporting Rule CSPA Comments 1.11.pdf

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Mr. Williams,

Attached please find comments submitted by the Consumer Specialty Products Association on the Children's Safe Products Reporting Rule - Rule Proposal Notice Chapter 173-334 WAC. Please contact me if you have questions regarding the comments.

Thank you,
Kristin Power

Kristin Power
Director, State Affairs – West Region
Consumer Specialty Products Association

900 17th Street Suite 300
Washington, DC 20006

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Cell (916) 838-3587

www.cspa.org

CSPA
Representing Household & Institutional Products
Aerosol - Air Care - Cleaners - Polishes
Automotive Care - Antimicrobial - Pest Management

January 5, 2011

Via E-Mail: jowi461@ecy.wa.gov

John R. Williams, Jr.
Washington State Department of Ecology
PO Box 47600
Olympia WA 98504-7600

Re: Rule Proposal Notice Chapter 173-334 WAC – Children's Safe Products Reporting Rule

Dear Mr. Williams:

The Consumer Specialty Products Association (CSPA)[1] appreciates the opportunity to review and provide comments on the Children's Safe Products Reporting Rule (Rule Proposal Notice Chapter 173-334 WAC). CSPA supports programs that are science-based and prioritized and that will promote sustainable innovation

CSPA members are committed to manufacturing and marketing safe products that are protective of human health and the environment while providing essential benefits to consumers. CSPA and our members support the broad goals of Green Chemistry and look forward to working with the Department of Ecology and other stakeholders in the state to help spur green chemical innovation and ensure that products are safe. CSPA has adopted its members' Green Chemistry commitment into the CSPA Principles for Chemicals Management Policy, which is available online at http://www.cspa.org/infocenter/our-issues/principles-for-chemicals-management-policy/.

CSPA member products improve the quality of human life and are necessary to protect the public health against dangerous diseases, infestation, and unsanitary conditions. CSPA

[1] CSPA is a voluntary, non-profit national trade association representing more than 240 companies engaged in the manufacture, formulation, distribution, and sale of chemical specialties products for household, institutional, commercial and industrial use. CSPA member companies' wide range of products includes home, lawn and garden pesticides, antimicrobial products, air care products, industrial, automotive specialty products, detergents and cleaning products, polishes and floor maintenance products, and various types of aerosol products. These products are formulated and packaged in many forms and are generally marketed nationally.

members are committed to providing products that are thoroughly evaluated for human and environmental safety and go through rigorous safety-based assessments before they are brought to market. CSPA members are also committed to clear and meaningful labeling on consumer products, *i.e.*, easily understood information to ensure safe and effective product use. CSPA has a product stewardship program called Product Care® that assists members in meeting these commitments. In addition, CSPA members are committed to the development of green products that are safe for human health and the environment. CSPA members routinely apply green chemistry and green engineering principles in their operations and have been honored with awards for their efforts.

The consumer products industry develops products that meet or exceed safety requirements of all state and federal agencies in the United States and Canada charged with regulating those products, including the California Department of Pesticide Regulation, the California Air Resources Board, and other state agencies, U.S. Consumer Product Safety Commission (CPSC), the U.S. Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the U.S. Food and Drug Administration (FDA), Health Canada, and Environment Canada.

Following are comments on specific sections of the regulation which express concerns reflecting our belief that the program should be science-based and prioritized.

WAC 173-334-070

The Department of Ecology understandably wants to consider degradation products of chemicals which meet the toxicity, persistence, bioaccumulativity or exposure criteria in the law. However, since the focus of the statute is on chemicals in children's products, a parent chemical which does not meet the criteria should not be listed unless it degrades under reasonably foreseeable conditions of handling or use of the children's product containing the parent chemical, including reasonably foreseeable ingestion by children. Potential degradation of a chemical under conditions not representative of actual handing and use should not be sufficient to list that chemical when it itself does not meet the toxicity, persistence, bioaccumulativity or exposure criteria.

In addition, degradation products should be subject to the same higher default reporting threshold, as discussed under "WAC 173-334-090" below.

WAC 173-334-090

CSPA urges the Department of Ecology to revise the notice requirement for the total amount of the chemical of high concern to children (CHCC) to a lowest level of 0.1% for all chemicals with a lower threshold for only certain chemicals. This approach is consistent with a number of state, federal and global regulations, including the European Union's implementation of the Globally Harmonized System (GHS) for product classification. In addition to applying a default threshold of 0.1% by weight, the EU GHS establishes chemical-specific thresholds that may be lower or higher than 0.1% based on sound

science and reliable information. This approach allows DOE to focus on specific chemicals while not overly burdening manufacturers.

Therefore, we request amendments to delete (e) (i) and (ii) for all listed chemicals, resulting in a default reporting de minimis of 1000 ppm (0.1%). This section should then also be amended to allow the Department to establish a lower or higher reporting requirement for certain listed chemicals if scientifically warranted.

WAC 173-334-120

CSPA urges the Department of Ecology to amend the definitions of manufacturers to better reflect the focus of the rule. Specifically, we request that the annual aggregate gross sales threshold be applicable to the manufacturer's gross sales of children's products **only**. This change more clearly reflects the intent of the Legislature in focusing on children's products and more accurately targets the pool of manufacturers responsible for compliance.

Summary and Conclusions

CSPA appreciates the opportunity to comment on the Children's Safe Products Reporting Rule. We acknowledge and support the efforts of the Department of Ecology staff to bring a new approach to reducing risks posed by chemicals in children's products. The Children's Safe Products Reporting Rule implements a prioritized approach to identifying and reporting chemicals of high concern to children. We appreciate the stakeholder outreach conducted by the Department to recognize and reflect legitimate concerns of the regulated community and respectfully request amendments to further focus the rule on the chemicals of high concern to children.

Please contact either of us if you have questions regarding our comments.

Respectfully submitted,

D. Douglas Fratz
Vice President,
Scientific & Technical Affairs

Kristin Power
Director,
State Affairs - West Region

cc: CSPA Scientific Affairs Committee Green Chemistry Task Force
CSPA State Government Affairs Advisory Committee
Bill Stauffacher, Stauffacher Communications

From: Jamie Fleece
To: Williams, John (ECY);
cc: Jamie Fleece; Tracy Hill; Karluss Thomas;
Subject: SEHSC Comments on WA DOE Children"s Safe Products Act Proposed Rule
Date: Friday, January 07, 2011 3:33:13 PM
Attachments: SEHSC Comments to WA DOE re CSPA Jan 7, 2011.pdf

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Mr. John Williams, Jr.,

Attached please find the Silicones Environmental Health and Safety Council's (SEHSC) comments on the State of Washington Department of Ecology (DOE) Proposed Children's Safe Products – Reporting Rule (WSR 10-22-017) (Proposed Rule).

Please feel free to contact me with any uestions regarding SEHSC's submission.

Thank you,
Jamie

Jamie L. Fleece
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January 7, 2011

Mr. John R. Williams, Jr.
Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600

Re: Comments on Proposed Children's Safe Products – Reporting Rule (WSR 10-22-017)

Dear Mr. Williams:

The Silicones Environmental, Health and Safety Council of North America (SEHSC)[1] is pleased to provide comments on the State of Washington Department of Ecology (DOE) Proposed Children's Safe Products – Reporting Rule (WSR 10-22-017) (Proposed Rule). For more than 30 years, SEHSC has promoted the safe use of silicones through responsible product stewardship and cutting-edge environmental, health and safety research. SEHSC appreciates this opportunity to offer the following comments and concerns regarding the Proposed Rule.

Timing and Basis of Review of Petition to Delist a Chemical

WAC 173-334-080 provides that a petition may be filed to delist a chemical from the chemicals of high concern to children (CHCC) list and that DOE will remove a chemical from the list if it determines that "credible peer-reviewed scientific information demonstrates that the chemical does not meet the required criteria for being on the CHCC list." We believe strongly that any decisions to add or remove a chemical on the CHCC list must be grounded in sound science and be based on a comprehensive review of the best available evidence. ***Accordingly, the rule should specify that DOE will use a weight-of-evidence approach that relies upon best available science to assess whether a particular chemical should be included on or removed from the CHCC list.***

WAC 173-334-060 indicates that DOE will "routinely revise the CHCC list no more frequently than once every two years," though it may add or remove chemicals outside the routine schedule if the directors of DOE and the Department of Health deem it appropriate, in accordance with the requirements of the Administrative Procedure Act. Because of the potential stigma and substantial reporting burden associated with being listed on the CHCC list, it is vital that DOE act upon delisting requests in a timely manner. We respectfully request that the rule provide for prompt, but principled decision making on delisting petitions and that any required changes to the CHCC list resulting from affirmed petitions be made as expeditiously as possible and that DOE should not be constrained by rule to a once-every-two-year schedule.

[1] The Silicones Environmental, Health and Safety Council of North America (SEHSC) is a not-for-profit trade association comprised of North American silicone chemical producers and importers.

The rule should specify that DOE will issue a decision on whether to grant a petition for delisting within 120 days of receipt of such petition. Such a decision must include a clear explanation of DOE's rationale for granting or denying the petition. The rule should indicate that delisting of a chemical from the CHCC list is immediately effective following DOE's publication of any decision to grant a delisting petition.

Exclusion for Unintentionally Added Substances

WAC 173-334-050 indicates that "[a] manufacturer must notify the department in accordance with this rule if a chemical on the CHCC list is present in a children's product component." WAC 173-334-090 provides that the lowest reporting range is "equal to or more than 40 ppm (0.004%) but less than 200 ppm (0.02%)."

It is unreasonable to require manufacturers of children's products to identify and disclose the presence of unintentionally added ingredients in product components. We note that the U.S. Environmental Protection Agency Toxic Substances Control Act (TSCA) regulations specifically exempt impurities (i.e., unintentionally present chemical substances) from premanufacture notification requirements.[2] As a practical matter, obtaining reliable information from raw material suppliers and/or component manufacturers on the potential presence and quantity of impurities in raw materials is extremely challenging. Likewise, it is impracticable and not economically feasible for product manufacturers to conduct testing for all CHCCs on each and every product component that comprise any children's product they manufacture. Notably, it would be very difficult to establish the validity of any such results given the high variability that can occur at the extremely low levels targeted by the Proposed Rule.

The rule should be amended to specifically indicate that reporting is only required for chemicals that are intentionally added to children's product components. Intentionally added chemicals should be defined to mean those chemicals that are deliberately used in the formulation of a product where the continued presence is desired in the final product to provide a specific characteristic, appearance, or quality.[3]

Modified Reporting Trigger

As noted above, WAC 173-334-090 establishes the low end of the minimum reporting range at 40 ppm (0.004%). That threshold is unreasonably low and is infeasible, particularly in light of the testing concerns noted above. A more appropriate threshold of 0.1% by weight would be consistent with the de minimis thresholds established under the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), U.S. Occupational Safety and Health Administration (OSHA) hazard communication standard (for carcinogens), and EU REACH legislation (Article 7 - registration and notification of substances in articles). U.S. EPA has indicated that the GHS threshold "reflects international consensus on appropriate de minimis concentrations below which governments do not find information useful for hazard communication on chemicals."[4] The Proposed Rule itself recognizes that "[r]eporting the

[2] See 40 C.F.R. 720.30(h)(1).

[3] Note - this definition is consistent with that set out in the draft California Safer Consumer Product Alternatives Regulations.

[4] 71 Fed. Reg. 66237 (Nov. 14, 2006).

presence of a CHCC does not establish that the product is harmful to human health."[5] Consistent with this recognition and in the absence of a risk-based, chemical-specific threshold determination, the reporting trigger of the Proposed Rule should align with that established under the above-referenced regulatory regimes. Raw material suppliers and product manufacturers have already expended (or are in the process of expending) significant resources to implement systems and programs to assure compliance with those requirements. An additional, different reporting threshold would pose significant burdens throughout the entire supply chain while providing information of questionable scientific reliability, validity, and utility.

The reporting trigger for CHCC-listed chemical substances in product components should be set at 0.1 percent by weight.

Basis for Octamethylcyclotetrasiloxane, CASRN 556-67-2 (D4) inclusion in WAC 173-334-140 CHCC List

SEHSC strongly opposes the inclusion of octamethylcyclotetrasiloxane, CASRN 556-67-2 (D4) on the WAC173-334-140 CHCC list. The Children's Safe Products Act provides the statutory criteria for inclusion on the list by defining a high priority chemical as "a chemical identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative by the department on the basis of credible scientific evidence as ***known to do one or more of the following***… cause reproductive harm… disrupt the endocrine system."[6]

Based on the background documentation DOE has posted on the chemical selection process, it appears that D4's designation as Category 1 on the initial EU list of candidate substances for evaluation as endocrine disruptors (the "EU candidate list") and as EU Reproductive Category 3 were the key toxicity factors in DOE's determination to add the substance to the CHCC list.[7] We strongly disagree that either of the referenced listings should be cited as providing the basis for concluding that D4 meets the statutory criteria for inclusion on the CHCC List.

We note that human health risk assessments recently conducted on D4 by the European Commission's Scientific Committee on Consumer Safety, the US Cosmetic Ingredient Review (CIR) Expert Panel, Health Canada and the UK Environment Agency all conclude that D4 does not pose a risk to humans.

With respect to whether D4 is known to disrupt the endocrine system, we note that the EU candidate list referenced above was developed as part of the EU Community Strategy for Endocrine Disrupters (the "EU Strategy") to establish a list of candidates "*for further evaluation.*"[8] Substances were included on the EU candidate list based on the result of a single study that indicated that a compound **might** have endocrine modulating activity.

The EU candidate list was not intended to be a list of scientifically confirmed endocrine disruptors. Further evaluation of the listed substances is a key element of the EU Strategy in

[5] WAC 173-334-010.
[6] RCW 70.240.010(6).
[7] See http://www.ecy.wa.gov/programs/swfa/rules/ruleChildPilotPhase.html
[8] Commission of the European Communities, Staff working document on the implementation of the "Community Strategy for Endocrine Disrupters" - a range of substances suspected of interfering with the hormone systems of humans and wildlife SEC(2007) 1635 (November 20, 2007).

determining whether a substance actually impacts endocrine function. Notably, there is no mechanism in place to remove substances from the list even if data from further, more advanced studies are available that contradict the initial finding that triggered the listing. There is also no process to integrate existing risk assessments by competent bodies into the EU Strategy. Thus, there is no way to incorporate the results of assessments that do not substantiate initial endocrine disruptor concerns for a particular substance.

On behalf of the European Commission, the Water Research Center (WRc-NSF) conducted a review of nine substances chosen from Category 1 of the EU candidate list.[9] The evaluation by WRc-NSF using additional data did not identify any of the nine substances as endocrine disruptors. The EU Commission's own scientific committee has endorsed the WRc-NSF analysis.[10]

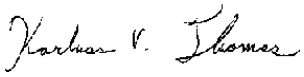
The EU has specifically indicated that the list is not final and it is not meant to be a "negative list" of substances.[11] Rather, it is meant to provide "a basis for gathering further data on endocrine disrupting effects of those substances and for their subsequent evaluation under the individual pieces of the Community legislation in order to address public concerns about these types of substances."[12]

Additional technical information is provided in the attached Appendix that supports our contention that D4 should not be included in the CHCC List on the basis of reproductive toxicity or endocrine disruptor concerns.

* * *

SEHSC appreciates your consideration of these comments regarding the Proposed Rule. Please feel free to contact me if you have any questions or concerns regarding this matter.

Sincerely,



Karluss Thomas
Executive Director, SEHSC

[9] WRc-NSF, Study on the scientific evaluation of 12 substances in the context of the endocrine disrupters priority list of actions, UC 6052 (2002). http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#report3

[10] European Commission Health and Consumer Protection Directorate, Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on "Two study reports on endocrine disrupters by WRc-NSF and BKH Consulting Engineers" (WRc-NSF Ref: UC 6052; BKH Ref: M0355037) Adopted by the CSTEE during the 40th plenary meeting of 12-13 November 2003.

[11] http://ec.europa.eu/environment/endocrine/documents/sec_2007_1635_en.htm

[12] Id.

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APPENDIX - **Summary and discussion of reproductive toxicity of Octamethylcyclotetrasiloxane (D4)**

Effects on fertility

The two-generation study is treated as the key study because it is of reliability score 1, the most recently conducted and the only two-generation study available. Other reliable reproductive studies are available, but they were one-generation or range-finder studies. Effects on female rat fertility were identified. These effects are characterized by the following:

1) An effect on fertility that occurs at ovulation (WIL Research, 1999) and apparently the result of suppression/delay in the pre-ovulatory luteinizing hormone (LH) surge and a reduced number of eggs ovulated (Quinn et al., 2007).
2) Decreases in the number of corpora lutea, number of uterine implantation sites, total number of pups born, and mean live litter size were noted in the one-generation general reproduction and fertility studies at high exposures.

Two multi-dose studies (0, 70, 300, 500 and 700 ppm) allow estimates of NOAELs. In one, (WIL Research, 1997a), reductions in reproductive parameters were recorded only at 700 ppm, while in the other study (WIL Research, 1998), reduced implantation sites and viable fetuses and increased pre-implantation losses were noted at 500 and 700 ppm. In addition, reduced numbers of corpora lutea were found at 300 ppm. However, as the reduction in corpora lutea was marginal at 300 ppm (14.6/dam vs. 16.2/dam in controls) without a clear exposure-related response, and within the range of values in historical control database, the NOAEL was considered to be 300 ppm. Similar reproductive changes were recorded in the two-generation study at 500 and 700 ppm but in addition increased estrous cycle length in F1 females at 700 ppm as well as increased pituitary gland weights were noted (WIL Research 2001a). Also in F1 females there were histopathological changes in ovaries and mammary gland at all exposure levels. However, when one considers that the histopathological changes were reported only in the F1 and not in the F0 generation, were minor and not clearly treatment-related except at 700 ppm, were similar in nature to those found in concurrent controls and considered to be a manifestation of the spontaneous, age-related waning of the female reproductive system in the rat then it is reasonable to consider 300 ppm as the NOAEL. Overall, the NOAEL for reproductive effects is 300 ppm (3640 mg/m3).

The following information should be taken into account for any hazard / risk assessment:

In the key inhalation two-generation reproductive toxicity study in rats (WIL Research 2001a), statistically significant reductions in mean live litter sizes and mean number of pups born were observed in the 500 and 700 ppm D4 groups for the F0 animals, and statistically significant reductions were noted for the first mating period in the F1 animals for the mean live litter size in the 500 and 700 ppm groups and for mean number of pups born in the 700 ppm group. Fertility indices were statistically significantly reduced in the 700 ppm group for the first F1 mating period. In the second F1 mating period, male and female fertility indices were statistically significantly reduced in the 500 and 700 ppm groups. The male and female fertility indices for the second F1 mating were also reduced in a non-exposure responsive manner in the 70 and 300 ppm groups, although the differences from the control group were not statistically significant. When the F1 males were paired with unexposed females, no effects on reproductive performance were observed, indicating that the alteration in the fertility indices was related to

effects in the females and not males. Microscopic evaluation of the ovaries, uterus, vagina, mammary gland and pituitary gland from the 0, 70, 300, 500, and 700 ppm F1 females suggested a subtle non-exposure responsive effect characterized by perturbation of the estrous cycle and accelerated reproductive senescence in F1 (but not F0) females at 70, 300, and 500 ppm, with a more obvious effect at 700 ppm. The NOAEC for reproductive toxicity was therefore 300 ppm, and the NOAEC for general toxicity was 70 ppm. The effects on fertility associated with inhalation exposure to high vapor concentrations of D4 are attributed to an effect on the female and specific to exposure surrounding the ovulatory phase (WIL 1999). Research to further define these associations has demonstrated that D4 exposure increases the incidence of females expressing a delayed/suppressed pre-ovulatory LH surge and ovulation (Control: 21%; 700 ppm D4: 58%; 900 ppm D4: 69%) (DCC 2002a; WIL 2001b). The pre-ovulatory LH surge and ovulation are critically connected in the rat as is well established in the literature. An insufficient or blocked pre-ovulatory LH surge fails to induce ovulation in the rat and results in the spectrum of fertility effects as seen with D4. The current understanding of estrus cyclicity and neural/hormonal regulation of ovulation in humans suggests that the effects of D4 on fertility as seen in the Sprague-Dawley (SD) rat are not relevant to humans.

It is important to consider the species differences in reproductive cycle regulation when assessing the potential relevance of the mode of action for D4 in inducing the noted reproductive effects in (SD) rats.

Reproductive Cycle Regulation in the Rat:

The rodent has a short estrous cycle that lasts for 4 or 5 days (Meites et. al., 1978). The rat estrous cycle is divided into four phases that roughly correlate to the 4 days of the estrous cycle: diestrus I, diestrus II, proestrous and estrus. In contrast to human females, about 12 ovarian follicles develop quickly in rodents with increases in follicle development and increases in estradiol secretion occurring on the afternoon of diestrus II through the time of ovulation on the day of estrus. Estradiol levels, therefore, are increased in the rodent for about 1.5 days of the normal estrous cycle. The pre-ovulatory LH surge, which occurs late on the afternoon and evening of proestrus, is brief, well timed, coupled to the light cycle, and driven by the brain (Nequin, et al., 1974). Following ovulation on the day of estrus, progesterone concentrations increase and remain elevated through the morning of diestrus II. The corpus luteum is very short lived in the rodents, lasting only about 2 days. Coitus in the rodent establishes a neuroendocrine memory circuit that results in diurnal and nocturnal surges of prolactin that persists for 11 to 14 days. These daily prolactin surges provide the signal for maintenance of the corpus luteum and pregnancy in the rodent (Gorospe and Freeman, 1984; Simpkins et al., 1983; Arey et al., 1989).

Reproductive Cycle Regulation in the Human Female:

Adult human females and females of other non-human primate species have long menstrual cycles, lasting approximately 28 days. The menstrual cycle is divided into three phases that are associated with underlying endocrine events: the follicular phase, the peri-ovulatory phase, and the luteal phase. The follicular phase begins with the onset of menses and continues for about 14 days, ending with ovulation. Low estrogens and progestins characterize the initial portion of this phase of the menstrual cycle that is associated with menses. While follicular development occurs during the entire follicular phase, it is not until about 7 days prior to ovulation that serum estradiol concentration begins to increase. This increase in estradiol is caused by the development of a single Graffian follicle. From this time until ovulation, there is a progressive increase in estradiol concentrations (Ross, 1981). During the peri-ovulatory period, an elevation

in serum estradiol (believed to be greater than 150 pg/ml) for 24 to 36 hours is required to induce a pre-ovulatory LH surge and the resulting ovulation of the ovum from the Graffian follicle. The LH surge is also the signal for lutenization of follicular cells into luteal cells of the corpus luteum. The peri-ovulatory LH surge is long, lasting 2.5 to 3 days (Ross, 1981). The luteal phase begins at ovulation and is predominated by increased secretion of progesterone and estrogens from the corpus luteum. After about 14 days, the corpus luteum dies (unless it is rescued by human chorionic gonadotropin (HCG) from the developing placenta). This death of the corpus luteum results in a precipitous decline of both estrogens and progestins that leads to menses. HCG is the signal for pregnancy in women (Ross, 1981).

Species Differences in Pre-Ovulatory LH Surge and Ovulation:

Major species differences have evolved with regard to the neuroendocrine control of ovulation (Plant, 2010). In the rodent, the timing of the preovulatory LH surge is determined by the brain, being triggered by a discharge of GnRH induced by a circadian neural signal that is coupled to the light dark cycle and gated by an action (positive feedback) of estradiol in the pre-optic area (POA) of the brain that, in part, is exerted on the population of kisspeptin neurons in the anteroventral periventricular nucleus (AVPV). Operation of this LH surge-inducing neuroendocrine system may be readily blocked by barbiturate anesthesia. During the perinatal period, the surge inducing system is disrupted (masculinized) by exposure to testicular androgens that remodel neuronal circuitry in the POA; a normal developmental event that leads to the male hypothalamus being unable to respond to the positive feedback of estradiol in the rat.

In the primate, on the other hand, the control system governing the preovulatory LH surge is 1) located in the medial basal hypothalamus (MBH)-pituitary unit and not the brain, 2) emancipated from control by the POA, 3) not subjected to programming by testicular androgens during perinatal development, and 4) resistant to the inhibitory action of barbiturate on neuronal activity. As in the rodent, ovarian estradiol exerts a positive feedback action on gonadotropin secretion and plays a key role in triggering the LH surge, but in contrast to the rodent any circadian input to the timing of the LH surge may be overridden by increasing the magnitude of the estradiol signal. The positive feedback action of estradiol in the monkey is mediated at the level of both the MBH (to discharge Gonadotropin-releasing hormone (GnRH) and pituitary (to enhance pituitary responsiveness to GnRH), but in women positive feedback at the level of the MBH may be less significant. In both species of primate, the hypothalamic and pituitary sites of the positive feedback action of estradiol appear redundant and spontaneous ovulation may be induced by pituitary feedback alone.

Mode of Action Investigations:

Exposure Period Criticality:

A study in which female SD rats were exposed during selected phases of the reproductive cycle was conducted (i.e. a —phased-female || study; WIL, 1999) to identify portions of the reproductive cycle where D4 may be exerting its effect on litter size. Knowledge of the timing of D4 action might provide insight into the potential mode of action of D4 on litter size in the SD rat. Four groups of female rats were exposed to D4 by whole body inhalation for 6 hrs/day according to the following schedule:

- Overall Phase: Groups of 24 female SD rats were exposed by inhalation to D4 at concentrations of 70, 300, 500, or 700 ppm (0.20, 0.87, 1.44, or 2.02 g/kg bw/day, respectively, assuming 100% absorption) beginning at least 28 days prior to mating and continuing through gestation day (GD) 19.
- Ovarian Phase: Sixty female rats were exposed to 700 ppm beginning 31 days prior to mating and stopping three days prior to mating.
- Fertilization Phase: Sixty female rats were exposed to 700 ppm three days prior to mating and continuing through GD3.
- Implantation Phase: Sixty females were exposed to 700 ppm from GD2 through GD5.

In the Overall Phase study, the following were the major observations: a reduction in the number of corpora lutea (500 and 700 ppm), reduction in the number of uterine implantation sites and fetuses (500 and 700 ppm), an increase in pre-implantation loss (500 and 700 ppm), and increased post-implantation loss (700 ppm). In the fertilization phase study, the number of corpora lutea, uterine implantation sites, and viable fetuses were reduced at 700 ppm (the only dose tested) while the mean pre-implantation and post-implantation losses were increased. The effects on corpora lutea and intrauterine survival were similar for both the fertilization phase in which exposure began 3 days pre-mating and continued through gestation day 3 and the overall phase in which exposure began 28 days pre-mating and continued through gestation day 19. No significant effects were noted on the number of corpora lutea or indices of intrauterine survival in females exposed at 700 ppm in the ovarian and implantation phase studies. In the ovarian phase study, when exposures began 31 days pre-mating and were terminated three days pre-mating, no effects were seen on uterine implantation sites, viable fetuses, or on any other reproductive parameter measured. This indicates the effects are totally reversible following cessation of exposure to high concentrations of D4.

The study results clearly demonstrated that the reproductive effect of D4 was dependent upon exposure to D4 during the ovulation/fertilization phase of the cycle.

Modulation of LH surge:

D4 was shown to inhibit the pre-ovulatory LH surge causing a delay in ovulation, persistent follicles and a prolonged exposure to elevated estrogen in the adult rat (Quinn et al., 2007). This study was conducted to assess the affect of D4 on the pre-ovulatory LH surge, to assess the ability of D4 to block or delay ovulation, and to evaluate the effects of exposure to D4 on other hormones related to normal reproductive function. Whole body vapor inhalation exposure of rats to D4 (700 or 900 ppm) resulted in an increased number of rats with suppressed pre-ovulatory LH surge compared to controls, where the number of the rats that failed to ovulate appeared to be within the normal range (25-30%) (Aschheim, 1983; Lu, 198; Cooper and Goldman, 1999). Evaluation of individual animal plasma LH data indicated that failure of a LH surge at 6 p.m. on the day of proestrus was accompanied by blocked or reduced ovulation. Additionally there were higher levels of plasma estradiol (E2) on the morning of presumptive estrus in most of the rats. Persistent mature follicles in D4-exposed animals continued to secrete estradiol and thus had higher E2 levels on the morning of estrus as a result of an attenuated LH surge and blocked ovulation. Conversely, control and D4-exposed rats that exhibited a LH surge, ovulated normally and had lower plasma E2 levels than the corresponding treatment group with a suppressed LH surge. In addition, the D4-treated ovulators had slightly higher E2 levels on the morning of estrus compared to the controls. This may be due to the slight trend towards retention of large follicles in both ovulating and non-ovulating treated animals.

Direct Endocrine Activity:

While D4 does have an apparent weak estrogenic/antiestrogenic in screening studies activity (Quinn et al., 2006), there are many observations in the reproductive studies (Dow Corning, 1996a; 1996b; 1997a; 1997b; 1997c; 1998a; Siddiqui et al., 2007; Meeks et al., 2007) that are inconsistent with this activity, indicating the very weak potency of this material. These observations are summarized below:

- ☐ No effects on male primary or accessory reproductive organs.
- ☐ No effects on sperm counts, sperm production rate, sperm motility or morphology.
- ☐ No effects on vaginal patency, balanopreputial separation, or anogenital distance.
- ☐ No visceral or gross abnormalities seen in any offspring.
- ☐ No effects on male reproductive performance.
- ☐ No effect on the ability of females to become pregnant after mating.
- ☐ No effects on the ability of the pregnant females to carry their litters to term.
- ☐ No effect on the females‘ behavior or ability to nurse their young or nurture the offspring to weaning.

Endpoints such as vaginal patency, balanopreputial separation, and anogenital distance are all sensitive endpoints designed to assess estrogenicity. Further, the lack of effects on male reproductive organs and sperm counts, sperm production rate, sperm motility or morphology also call into question any role for inherent D4 estrogenicity in the mode of action for reproductive effects.

Developmental toxicity

Two scientifically reliable studies (one in rat and one in rabbit) conducted in the same year are available for evaluation of developmental toxicity. These studies gave the same negative results for effects on developmental toxicity, including teratogenicity. In the key inhalation developmental toxicity study in rabbits (IRDC, 1993a), D4 did not affect fetal developmental and the NOAEC for this endpoint was therefore greater than the highest concentration tested (500 ppm; 6066 mg/m3). The NOAEC for maternal toxicity was 300 ppm based on reduced food consumption in the highest dose group. In the inhalation study in rats (IRDC, 1993b), the NOAEC for maternal toxicity was 300 ppm based on reduced food consumption and body weight in the highest dose group, 700 ppm. No developmental toxicity was noted at any exposure concentration tested, 700 ppm. In addition, no developmental or teratogenic defects were noted in the 1- and 2-generation rat reproduction studies.

Classification:

The available data suggest that D4 should be classified as Reproductive Category 3 for its demonstrated effects on female fertility in rats. This is derived from research that has shown the fertility effects are associated with exposure of the female rat during the critical ovulatory phase and that exposure during the ovulatory phase induces a delay/suppression of the pre-ovulatory LH surge and subsequent ovulation. Differences in the regulation of the pre-ovulatory LH surge, and the criticality of timed events with regard to rat versus human reproductive control, support that the observed high-dose effect of D4 on female rat fertility should not be considered relevant to humans. The available data suggest that D4 does not require classification for effects on development or male fertility.

From: Hackman, Andy
To: Williams, John (ECY); Kraege, Carol P. (ECY); Williams, John (ECY);
cc: William Alkire; jgregorich@toyassociation.org;
Subject: TIA"s Final Comments on CSPA Proposed Rule
Date: Thursday, January 06, 2011 3:02:46 PM
Attachments: TIA Comments on CSPA Rule FNL.pdf

Dear John,

Attached please find a final copy of TIA's Comment on the Children's Safe Products Act – Proposed Reporting Rule. We appreciate your consideration of the these issues and look forward to continuing to work with you and the Department of Ecology on the development of a Final Rule that achieves the ob ectives of the CSPA and is a workable common-sense approach.

Please do not hesitate to contact me and Joseph Gregorich, TIA's Director of State Government Affairs, with any uestions or to discuss potential solutions to the issues raised in these comments.

Respectfully submitted,

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January 6, 2010

John R. Williams, Jr.
Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

RE: TIA Comments on Children's Safe Products Act – Proposed Reporting Rule

Dear Mr. Williams,

The Toy Industry Association appreciates this opportunity to provide input on the key concerns and recommendations with regard to the Department of Ecology's (DoE) Children's Safe Products Act Proposed Reporting Rule.

TIA applauds the hard work of the Department staff to outreach to impacted stakeholders and appreciates the opportunity to provide comments on these Proposed Regulations. TIA looks forward to working with you and DoE staff in helping to shape a final regulatory proposal that fosters innovation and protects efficient commerce.

TIA is a not-for-profit trade association representing more than five-hundred (500) toy makers, marketers and distributors, large and small, located throughout North America. TIA's members account for approximately 85% of the annual U.S. domestic toy market of $21.6B, according to research from the NPD Group. The Toy Industry Association 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 recognized and used as models around the globe. Our mission is also to educate industry on these standards, and also educate parents and caregivers on choosing appropriate toys and how to ensure safe play.

While TIA recognizes that there has been a significant effort to reach compromise between different viewpoints in these Proposed Regulations, we would like to highlight comments and concerns with the current proposal that we believe are necessary to be addressed before a final workable regulatory draft can be accomplished. These comments and concerns are as follows:

1. **Threshold 40 ppm Trigger Level (WAC 173-334-090)**

TIA applauds the inclusion of a trigger reporting level for Chemicals of High Concern to Children (CHCC); as this provides essential testing and compliance guidance to product manufacturers. Without a trigger level companies would always be unsure of their ability to validate compliance with the law due to constraints of testing, new detection technologies, and analytical test methods. In essence, a company would "never be able to prove a negative" given continual advances in detection technologies.

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Additionally, per our comments below, a trigger level remains necessary in addition to focusing the Rule on intentionally-added ingredients.

However, per TIA's earlier comments, a 1000 ppm trigger level is more appropriate than the lowest reporting trigger threshold of 40 ppm. The threshold of 1000 ppm is internationally recognized and used as a trigger level under REACH Article 7. Additionally 1000 ppm (0.1%) had been proposed as acceptable in the California Green Chemistry Regulations (CA DTSC – R-2010-05) and this level is becoming a uniform state standard for these types of programs.

As the trigger level relates to exposure, migration studies on common plastics show that materials with total content levels f any specific chemical below 1000 ppm but above 40 ppm result in extremely minimal migration. Specifically, in common plastic materials, the levels of migration for most substances are between 0.01 and 0.005 mg/dm² in standard migration models. This range represents an extremely low level of exposure and does not pose a health risk. Focusing content levels below 1000 ppm is not an efficient use of the Department's or a company's resources (given extremely minimal exposure) and is not a "common-sense" approach to this Rule – as directed in the Governor's April 1, 2008 veto message for the CSPA.

While TIA understands that the Department is not attempting to set a "health-based" trigger level, we assert that reporting under this program will be construed by the public as some indication of safety of a product and, therefore, reporting should relate to some protective estimate of the actual level of exposure, consistent with international reporting thresholds. Therefore, DoE should set the lowest trigger level threshold at 1000 ppm.

2. **Trigger Level Application to Total Product by Weight (WAC 173-334-90):**

The trigger level should be applied to the total product by weight, rather than to components. The key impact of establishing the trigger level is to establish a level below which exposure to a CHCC is not relevant for reporting of exposure. Therefore total exposure from a product should be the key determinant to applying a trigger level.

Application of the trigger level to components distorts the aggregate exposure resulting from a product. The trigger level should apply to the total exposure and threat of adverse impact from the entire product. The trigger levels proposed in this rule are in stark contrast with REACH Article 7 that articulates that the 0.1% de minimis (Trigger) level applies to the total product by weight. In fact, recent REACH legal guidance indicates:

> **"an article is to be understood as the article as produced or imported. It may be very simple, like a wooden chair but could also be rather complex, like a computer, consisting of several parts, which are also considered articles when produced or imported.[1]" [Emphasis Added]**

Therefore, to be consistent with this approach to articles, in international regulations, the Rule should be amended in this Section to apply to a total product by weight.

[1] European Commission. Ref. Ares(2010)826118 - 17/11/2010. http://chemicalwatch.com/downloads/Opinionofthelegalservice-Article7and33REACH.pdf

3. "Reasonable and Foreseeable" (WAC 173-334-070):

TIA is very concerned that, since the Preliminary Rule, the concept of determining, "credible potential for exposure" has been removed from the Rule in Section 173-334-070. Evaluating for credible exposure is essential for this Rule to be science-based and TIA urges this language from the Preliminary Rule to be included in the Final Rule; as it relates to chemical prioritization. Further, the concept credible potential for exposure is similar to the concept of "reasonable and foreseeable use" of a product that must also be included in this Rule in Section 173-334-070.

Toy manufacturers and toys are regulated under various federal statutes, including: the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), the ASTM Safety Specification on Toys (which was adopted as a federal standard on February 10, 2009), and the comprehensive Consumer Product Safety Improvement Act (CPSIA) signed into law in 2008. These frameworks of regulation rely on the concept of a "reasonable and foreseeable" criterion to evaluate whether or not a product will expose a consumer to a chemical. This criterion acknowledges the "real-world" planning, design, and control that responsible companies must undertake to prevent exposure to a chemical; and the "real-world" use patterns of products.

Additionally the U.S. Consumer Product Safety Commission (CPSC), in August 2009, once again endorsed the reasonable and foreseeable exposure criterion in regulation through the "Children's Products Containing Lead; Interpretative Regulations on Inaccessible Component Parts" (16 CFR Part 1500). Specifically the Regulations stipulate:

> "**Use and abuse tests are appropriate for evaluating whether lead-containing component parts of a product become accessible to a child during normal and reasonably foreseeable use and abuse of the product by a child. The purpose of the tests is to simulate use and damage or abuse of a product by children and to expose potential hazards that might result from use and abuse.[2]" [Emphasis Added]**

As such, this concept must be included as guidance in this Section; so that a company can reasonably evaluate exposure from their product for the purpose of reporting in the correct exposure-based tier of products.

4. "Intentionally-Added Ingredients" (WAC 173-334-040 & 090):

In addition to the inclusion of a reasonable trigger level, there must be a clear indication in Sections 173-334-040 and 090 that the scope of the reporting would only apply to "intentionally-added ingredients". Further, intentionally-added ingredients should be defined as:

> "intentionally-added ingredient" means a chemical that is formulated into or intentionally included by the final product manufacturer to serve a functional purpose in the end-product."

The concept of focusing on the intentionally-added ingredients is supported by the WA State Department of Health (DoH)/University of WA Report, dated 23 July 2010, submitted to the DoE (Task

[2] 16 CFR 1500.50–1500.53.

1, C; page 4), which indicates that "…27 chemicals on the list are probably not added as ingredients during final production of children's products." They seem to further suggest that these chemicals will be excluded when they state that… "The broad definition of "intentionally added" proposed by Ecology should cover the range of these chemicals in children's products."

DoE also acknowledged in the "Phase 3 Report" that "the focus should be on those chemicals that are intentionally added to children's products". This statement is correct and should be the focus of activity for the Rule. As stated above, the "Phase 3 Report" clearly indicates that 0.1% (1000 ppm) is a valid threshold for determining that a chemical is intentionally-added. TIA requests that the Rule be amended to focus on "common-sense" application of the Rule to **only** intentionally-added ingredients.

5. **Exposure Tiers for Reporting (WAC 173-334-120):**

TIA supports non-reporting for Tier 4 products (inaccessible components); unless there is a specific need for information determined by DoE, which would be subject to public notice and comment. The concept of exempting internal components is consistent with the U.S. Consumer Product Safety Commission (CPSC) regulation of lead in children's products under the CPSIA, which states:

> **"Some children's products may be exempted or excluded from the new lead limits particularly if the only parts containing lead are inaccessible. A component part is not accessible if the component part is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product.[3]" [Emphasis Added]**

This concept of exempting internal components is also consistent with Canada's recently proposed lead regulations. Specifically they exempt:

> **"Components of products that are required to store, generate, or conduct an electrical current, such as batteries, electrical solder and flux, and cables, provided that these components are not accessible to children.[4]" [Emphasis Added]**

TIA also specifically requests that the Rule be made clear and indicate that - reporting is not necessary for inaccessible components, even in products intended for children 0-3 - that would be reported as a Tier 1 product. This stipulation would make clear the application of Tier 4 reporting and its relationship to inaccessible components.

Additionally, TIA requests that all electronic components should be exempted, to be consistent with federal and international regulatory approaches to exposure. Federal precedent exists for exclusion of Restriction of Hazardous Substances Directive (RoHS) compliant electronic components, which in turn forms a reasonable model for excluding reporting all electronic components under this Rule. Specifically the CPSC States:

> **"To the extent that certain electronic component parts cannot be made inaccessible, the staff has reviewed the exemptions granted under other directives including European**

[3] http://www.cpsc.gov/about/cpsia/faq/101faq.html
[4] http://www.hc-sc.gc.ca/cps-spc/legislation/consultation/summary-eng.php

Union Directive 2002/95/EC (EU RoHS), and Korea Act for Resource Recycling of Electrical and Electronic Equipment and Vehicles (Korea RoHS), to evaluate possible exemptions when substitution for lead was not possible due to scientific and technical considerations.[5]"

Under this approach the CPSC adopted the same considerations and exemptions from RoHS. Given international acceptance of RoHS regulation of electronic components (and federal endorsement of that approach) exempting all electronic components in the Ruleis justified and should be made consistent with federal and international regulations.

Finally, TIA also requests that DoE provide a guidance document to aid companies in determining which of their product types fall into each exposure-based reporting tier. Per the comments above, this guidance must reference "normal and reasonably foreseeable uses and abuses" scenarios that might result in exposure.

6. **Aggregate Gross Sales Tiers for Reporting (WAC 173-334-120):**

Per our previous comments, TIA suggests to the Department that "Aggregate Gross Sales" is not an appropriate or relevant indicator for phase-in of the reporting requirements. Aggregate Gross Sales does not necessarily equate to impacts on human health or safety. Aggregate Gross Sales is not related to actual product exposure and it is inequitable, from a safety perspective, to be a primary determinant in what products report first. Aggregate Gross Sales application of the reporting requirement to companies could be viewed as discriminatory and unconstitutional under the statute. Regardless of market-size those individual products that result in exposures of greatest concern should report first. Exposure does not relate to sales volume in the market place and in some cases, smaller sales volume products may have fewer controls to prevent exposure to a CHCC.

Finally, as currently drafted the Rule is unclear under the annual Aggregate Gross Sales volume reporting scheme, if the sales values that would trigger timing for reporting are for: (1) all products that a company sells (including non-children's products), (2) only children's products (as defined by the statute), or (3) just the children's product that contains the CHCC. TIA requests that, if the Department refuses to remove the Aggregate Gross Sales reporting mechanism, that it make clear that the annual Aggregate Gross Sales values used to determine size, relate **only** to the children's product containing the CHCC that would trigger reporting.

This is justified because, using only the sales values of the products containing the CHCC for the size tier of reporting, at least, attempts to link actual sales volume of a product that ***might*** result in exposure to a CHCC. As discussed above simply using the size of a company to phase-in reporting is not justified and could be judged as discriminatory.

7. **Chemicals remain on the reporting list that should be excluded for data quality and scientific consensus concerns (WAC 173-334-140):**

TIA provided a significant analysis of the Reporting List of Chemicals of High Concern (CHCC) performed by Hazardous Substance & Waste Management Research, Inc. on June 4, 2010 and May 13,

[5] 6990 Federal Register. Vol. 74, No. 28. Thursday, February 12, 2009.

2010. However, despite this extensive analysis there appears to be little consideration of this input; nor does there appear to be any response from DoE to the issues raised in that analysis - addressing why these concerns have not been considered. TIA understands that tens of thousands of chemicals could meet the criteria for selection established in the statute, but asserts that DoE must respond to the analysis that has been provided and declare why certain chemicals that lack sufficient scientific consensus or data quality remain on the CHCC list.

Specifically, TIA remains concerned that 27 of the 59 chemicals do not appear to have a justification for how they reached the level of concern established for this program and have not been justified in their inclusion on the CHCC in contrast to the thousands of other chemicals that could qualify under the criteria stipulated in the CSPA. TIA documented strong rationale why the following chemicals have not been proven through open and authoritative data to exhibit relevant characteristics of concern, lack scientific consensus, are inaccessible, or have been approved as safe by authoritative bodies (GRAS list).

Antimony & compounds	Database Concerns
Butylated hydroxyanisole; BHA	GRAS
Methyl paraben	GRAS
Molybdenum & compounds	Database Concerns
Propyl paraben	GRAS
n-Butanol	Not Consensus CMR
Styrene monomer	Not Consensus CMR
Phenol	Not Consensus CMR
Solvent Yellow -14	Not Consensus CMR
Nonylphenol	Not Consensus CMR
2-ethyl-hexyl-4-methoxycinnamate	Endocrine Disruptor only
4-Nonylphenol; 4-NP	Endocrine Disruptor only
4-tert-Octylphenol	Endocrine Disruptor only
Benzophenone-2 (Bp-2)	Endocrine Disruptor only
Butyl paraben	Endocrine Disruptor only
Estragole	Insufficient Evidence
Ethyl paraben	Endocrine Disruptor only
Hexabromocyclododecane	Insufficient Evidence
Hexachlorobenzene	Insufficient Evidence
Hexachlorobutadiene	Insufficient Evidence
Octamethylcyclotetrasiloxane	Endocrine Disruptor only
p-Hydroxybenzoic acid	Endocrine Disruptor only
Pentachlorobenzene	Endocrine Disruptor only
Tetrabromobisphenol A	Insufficient Evidence
methyl ethyl ketone	Not Consensus CMR
4-octylphenol	Not Consensus CMR
perfluorooctanyl sulphonic acid PFOS	Not Consensus CMR

The information submitted to the DoE and presented in Appendix B of the Washington State DoH/University of Washington Report, dated 23 July 2010, appears to have evaluated in detail at least

some of the chemicals on the draft list. However, rationale is presented only for those three chemicals that this Rule has removed from the proposed CHCC list. TIA requests a justification as to why the above chemicals remain on the CHCC list and how they were raised to the level of concern exhibited by the other chemicals on the CHCC list. Further, TIA continues to substantiate the analysis by Hazardous Substance & Waste Management Research, Inc., as contained in the previous analysis submitted to DoE that demonstrates these chemicals should not require reporting, and requests a response to this analysis.

8. **Conclusion:**

TIA appreciates the hard work that has gone into the development of this Rule and outreach to stakeholders. TIA also appreciates that some elements of exposure have been taken into consideration in the development of this Rule. However, as discussed above, several issues of concern require additional modifications to the Rule in order for it to result in a process that is feasible in implementing the CSPA.

TIA remains committed to working to ensure that a Final Rule provides a workable solution to the mandate of the CSPA, and looks forward to continuing to work with you on these outstanding issues. TIA thanks you and DoE again for this opportunity to comment on the Preliminary Regulations. Please feel free to contact TIA directly via Andrew Hackman at: 646-520-4851 or ahackman@toyassociation.org, if you have any questions or concerns about these comments or would like to discuss in more detail.

Respectfully,

Andrew Hackman
Senior Director of State Government Affairs

From: Tom Myers
To: Williams, John (ECY);
Subject: WA Children*s Safe Products Act - draft reporting rule
Date: Friday, January 07, 2011 12:21:16 PM
Attachments: Comments to WA Draft Reporting Rule 010711 (scanned).pdf

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John,

Thanks for all your work on the draft reporting rule. Attached are the comments of the Personal Care Products Council. If you have any questions, or need any additional information, please let me know.

Best,

Tom

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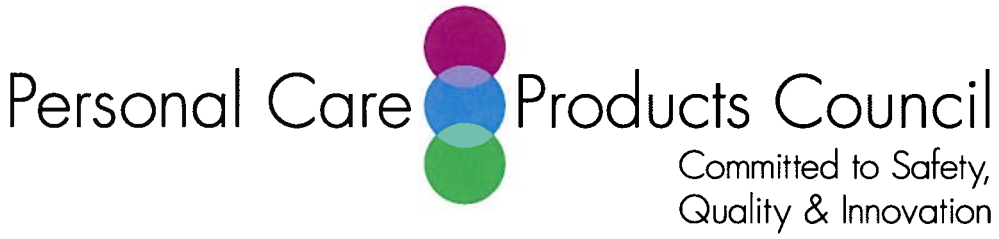

January 7, 2011

John R. Williams
Washington State Department of Ecology
W2R HQ
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Olympia, WA 98540-7775

Re: Comments on Draft Reporting Rule for Children's Safe Products Act of 2008

Dear Mr. Williams,

The Personal Care Products Council (Council)[1] is pleased to submit the following comments on the Washington Department of Ecology's (DOE) proposed reporting rule,[2] which is intended to implement the reporting requirements of the Children's Safe Product Act of 2008 (Act). Our member companies are involved in the manufacture and distribution of over-the-counter (OTC) drug products, cosmetics, toiletries, fragrances, and ingredients in Washington and throughout the United States, and therefore have a strong interest in the scope and applicability of these regulations.

Our comments request DOE to address the following key points:

1. Clarify the scope of the term "children's products"
2. Remove parabens from the CHCC list
3. Eliminate the trigger levels for reporting ranges
4. Define "intentionally-added" and ensure Act only applies to such chemicals

1. CHILDREN'S PRODUCTS

The Children's Safe Product Act of 2008 regulates "Children's Products", which are defined to include toys, children's cosmetics, children's jewelry, and products that help a child with sucking, teething, to

[1] Based in Washington, D.C., the Council is the leading national trade association representing the $250 billion global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products that millions of consumers rely on everyday, from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance, member companies are global leaders committed to product safety, quality, and innovation. The Council was previously known as the Cosmetic, Toiletry, and Fragrance Association (CTFA).

[2] Chapter 173-334 WAC Children's Safe Products – Reporting Rule (October 22, 2010).

facilitate sleep or feeding, or worn as clothing.[3] The Act goes on to define "Cosmetics" to specifically exclude food and drugs.[4]

Presumably, based on these definitions, the Washington legislature intended to exclude drugs, including over-the-counter (OTC) drugs, from the definition of "children's products" and thus from regulation under the Act. The Council believes this is the correct interpretation of the Act and legislative intent, and encourages DOE to state as much in its proposed rule. The legislature obviously recognized that drugs are already stringently regulated by a robust and comprehensive regulatory scheme administered by the U.S. Food and Drug Administration (FDA), and introducing duplicative or even conflicting regulations would do nothing to enhance the health or welfare of children in the State of Washington.

In addition, the Council recommends that DOE clarifying the term "Children's Products" (and possibly the term "Cosmetics") in its proposed rule to more fully address products that are both drugs and cosmetics. Consumer products that are both cosmetics and drugs (i.e., foundation with SPF) are required by FDA to fully comply with all drug regulations. As such, for the same reasons stated above as to why drugs are excluded from the scope of the proposed rule, the Council believes that products that are both a cosmetic and a drug should likewise be excluded. The Council therefore strongly recommends that DOE modify the definition of "Children's Product" or "Children's Cosmetics" to specifically exclude drugs, including cosmetic/drugs, from regulation.

2. PARABENS

The Council recognizes that the foundation of chemical hazard-based product regulation is the establishment of lists of priority chemicals either prohibited or limited in the specific products being regulated. We disagree, however, with the concept that some chemicals are so dangerous that exposure at any level poses a hazard, preferring instead a data-based risk assessment approach.

Nevertheless, we understand that, in some cases, a hazard-based approach may be more efficient. In such cases, we believe that industry and the public deserve a scientifically-based, transparent process for creating the list. Chemicals appearing on the list should fulfill a defined set of requirements and the steps leading to inclusion should be open to public scrutiny. Without such transparency, the regulated community cannot challenge the conclusions, and due process is denied.

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[3] §70.240.010(3)(a).

[4] §70.240.010(4).

From the publicly available information, the Council was unable to determine if such a process had been followed. DOE's website lists a vague prioritization process involving review of the literature for characteristics including detection in human tissues, regulation by other jurisdictions, presence on one or more "lists" of toxic chemicals published by reputable authorities, and/or demonstration of human and/or environmental toxicity as measured through scientifically validated tests. None of the steps in this process are prioritized over the others, leading to the conclusion that a chemical requires only one of these properties, and perhaps others, to appear on the list.

Given the proliferation of chemicals in our society, they are often detected in human tissues and urine. However, simply detecting a chemical does not make it hazardous. A good example of this would be parabens. Although parabens have been detected in human tissues and urine in extremely low concentrations,[5] the concentrations at which they were detected have not been associated with any health effects in children or any other population.[6] In fact, their risk to human health remains purely theoretical, and no tissue concentrations have ever been linked to human health impacts.

The major health concern related to paraben exposure relates to their classification as potential "environmental estrogens." These concerns originated from the finding that parabens exhibit very weak estrogenic activity in experimental models.[7] However, evidence that these findings have any significance *in vivo* is mixed at best. There is no consistent evidence that exposure to parabens, even at doses much higher than those associated with human food or cosmetic exposure, is associated with toxic effects in developing or neonatal rats, and several studies have failed to show effects of parabens on rats exposed *in utero*. Parabens are federally approved as food and cosmetic preservatives, and methyl and propyl paraben – both of which are listed by DOE as a CHCC – are on the FDA's "Generally Recognized As Safe" list as Catoegory 1 substances, which according to FDA means:

> *There is no evidence in the available information on [the substance] that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or might reasonably be expected in the future.*

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[5] Calafat,AM, Ye X, Wong AY, Bishop AM, Needham LL. Urinary concentrations of parabens in the US population: NHANES 2005-2006. Environ Health Perspect 2010, 118: 679-685.

[6] Cowen-Ellsbury CE, Robison SH. Refining aggregate exposure: example using parabens. Reg Toxicol 2009: 55, 321-329.

[7] Witorsch R and Thomas J. Personal care products and endocrine disruption: a critical review of the literature. Crit Rev Toxicol 2010, 40: 1-30.

In fact, FDA has examined parabens in detail and conclusively determined them to be safe. It is difficult to reconcile how FDA can classify parabens as GRAS, as noted above, yet DOE can simultaneously classify them as a CHCC. It is instructive, perhaps, to cite FDA's public statement regarding to paraben safety:

> *FDA is aware that estrogenic activity in the body is associated with certain forms of breast cancer. Although parabens can act similarly to estrogen, they have been shown to have much less estrogenic activity than the body's naturally occurring estrogen. For example, a 1998 study (Routledge et al., in Toxicology and Applied Pharmacology) found that the most potent paraben tested in the study, butylparaben, showed from 10,000- to 100,000-fold less activity than naturally occurring estradiol (a form of estrogen). Further, parabens are used at very low levels in cosmetics. In a review of the estrogenic activity of parabens, (Golden et al., in Critical Reviews in Toxicology, 2005) the author concluded that based on maximum daily exposure estimates, it was implausible that parabens could increase the risk associated with exposure to estrogenic chemicals.* ***FDA believes that at the present time there is no reason for consumers to be concerned about the use of cosmetics containing parabens.*** (Emphasis added).[8]

Moreover, the Cosmetic Ingredient Review (CIR)[9] also reviewed the safety of methylparaben, propylparaben, and butylparaben and concluded they were safe for use in cosmetic products . In 2005, CIR re-opened the safety assessment for parabens to examine more recent exposure estimates and risk assessments for cosmetic uses. After considering, in particular, the potential exposure to sensitive subpopulations (i.e., women and infants), CIR once again determined that there was no need to change its original conclusion that parabens are safe as used in cosmetics.

Butyl, ethyl, methyl and propyl paraben are currently listed by DOE as CHCCs. The Council believes these listings are in error, based on the medical literature available, and recommends that they be removed from the CHCC list.

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[8] http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm128042.htm.

[9] The CIR is an industry-sponsored organization that reviews cosmetic ingredient safety and publishes its results in open, peer-reviewed literature. FDA participates in the CIR in a non-voting capacity. The Cosmetic Ingredient Review (CIR) Expert Panel is an independent, independently-funded, panel of scientific experts – with U.S. Food and Drug Administration officials and a representative of the Consumer Federation of America participating as liaison members – that regularly assesses the safety of numerous cosmetic ingredients and publishes its findings in open, peer-reviewed literature.

3. *DE MINIMIS* / TRIGGER LEVELS

The Council is very concerned about the trigger level reporting ranges specified in the proposed rule. It seemed clear, prior to issuing the proposed rule, DOE only intended to recommend reporting ranges for CHCCs exceeding 0.1% by weight. In its Phase 3 Report, DOE stated:

> *Concentration of chemicals of concern present at 0.1% in product components (1000 ppm) is a commonly accepted value, used by jurisdictions such as the European Union, to indicate that a chemical is intentionally added to a product... As a result, Ecology chose not to accept the recommendations of DOH/PEHSU with regard to individual reporting trigger levels for each chemical. Instead, Ecology chose to bracket reporting ranges around the commonly used value of 0.1% (1000 ppm) and the lower values recommended by the DOH and PEHSU for some chemicals.*[10]

In other words, reporting generally would be required only for those intentionally-added chemicals that exceed 0.1% by weight. Yet DOE's proposed rule seems to suggest that reporting is required for every chemical at concentrations above 40 ppm. This would be an extremely onerous requirement, and there is no corresponding public health protection rationale for such a requirement. Nor is there any explanation or justification as to why DOE modified its position from the one stated in the Phase 3 Report.

The Council suggests DOE clarify in the rule that reporting is mandatory only when intentionally-added CHCC are present at levels above the 0.1% *de minimis threshold*. This would make the rule consistent with a majority of state, federal and international regulations, including the European Union's R.E.A.C.H. framework, which employ a 0.1% by weight *de minimis* threshold for reporting.

4. INTENTIONALLY-ADDED CHEMICALS

It seems clear from the Act that the legislature intended to regulate only those CHCC that are *intentionally-added* to children's products. The notice requirements of the Act, for example, state that a manufacturer should supply a chemical's Chemical Abstract Service registry number, a description of the

[10] http://www.ecy.wa.gov/programs/swfa/rules/pdf/p3text.pdf

chemical's function in the product, the amount of the chemical used in the product, etc.,[11] all of which seem to indicate a focus on chemicals that are intentionally-added by the manufacturer.

This interpretation is bolstered by DOE's Phase 3 Report, which appears to confirm that the focus should be solely on intentionally-added chemicals:

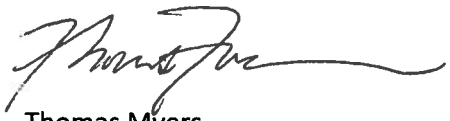
> *Ecology evaluated this recommendation and determined that for practical reasons, the focus should be on those chemicals that are intentionally added to children's products.* [12]

Unfortunately, "intentionally added" is not defined in the draft rule, nor is its application made clear. As such, the Council strongly recommends clarifying the regulations to specifically include the definition and concept of intentionally-added chemicals.

Conclusion

The Council would like to thank DOE for the opportunity to provide comments on the proposed reporting rule, and welcomes the opportunity to work with DOE on this and future rulemakings. Our industry recognizes the critical need to construct a chemical management program that is workable from the outset, with a narrowly drawn scope and requirements that are not cost-prohibitive, in order to improve public health and the environment in the State of Washington.

Sincerely,



Thomas Myers
Associate General Counsel

[11] http://apps.leg.wa.gov/RCW/default.aspx?cite=70.240.040

[12] http://www.ecy.wa.gov/programs/swfa/rules/pdf/p3text.pdf

From: Thomas Head
To: Williams, John (ECY);
cc: Jennifer Kirk; Peggy Fowler;
Subject: Walmart Comments on CSPA Reporting Rule
Date: Friday, January 07, 2011 3:39:31 PM

January 7, 2011

John Williams
Department of Ecology *submitted via email: john.williams@ecy.wa.gov*
PO Box 47600
Olympia, WA 98504-7600

Once again, Walmart appreciates the opportunity to provide comments to the Department of Ecology on the proposed Children's Safe Products Reporting Rule. In addition to the comments below, we applaud the state of Washington for adopting this innovative approach to rulemaking and appreciate the opportunity to participate.

WAC 173-334-040

We support the definitions provided within this section as written.

WAC 173-334-050

We support the stated ob ective of identifying chemicals through the CHCC list, but we continue to believe that information can only be collected and provided on chemicals that are intentionally introduced during the manufacturing process.

WAC 173-334-060

We support the proposed fre uency of revision of the CHCC list, but believe the rule should specifically provide for public comment periods on each chemical introduced in order to identify ade uate time re uired for manufacturers in the different product categories to begin reporting.

WAC 173-334-090

We support the Department's approach in section (1)(e) to collect information on CHCCs at a component level. It is unnecessarily difficult to aggregate concentration values in complex products. The ECHA continues to struggle with this in applying provisions of REACH to consumer products. The Department should look to leverage ECHA guidance on calculating concentrations of SVHCs.

WAC 173-334-100

We agree with the proposed definition of a manufacturer. We ask the last paragraph of section 173-334-100 be clarified, as we believe foreign manufacturers should be allowed to satisfy Notice obligations on behalf of domestic responsible entities without precluding enforcement against importers or brand owners in the sections above.

WAC 173-334-120 4 (a)

The scope of products in Tier 1 beyond personal care should be clarified. We recommend use of the federal definition of "Mouthable" provided in Section 108 of the CPSIA to more appropriately focus on exposure in this vulnerable population.

"A toy can be placed in a child's mouth if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the toy can only be licked, it is not able to be placed in the mouth. By definition, if a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth."

In Tier 2, we agree with the definition provided in children's products intended to be in prolonged (more than one hour) direct contact with child's skin, however the provided examples should remain consistent to the "class" description provided in GS1 Global Product Classifications. We recommend removing the proposed example of 'car seats', but keep the class of "clothes, ewelry and bedding".

173-334-130 Enforcement

While we agree that a manufacturer is responsible for knowing the amount of CHCCs, importers and private brand owners lack the direct knowledge and control of actual manufacturers. As responsible entities, importers and private brand owners must rely on records and representations of others to obtain reasonable assurances in providing notice under the rule. Our experience with similar obligations in Europe under REACH Article 33 demonstrates how extended global supply chains of complex products must rely on declarations and certifications to pass information on SVHCs from component suppliers through retailers to consumers. The rule should reflect the differences in due diligence standards for responsible entities without direct knowledge.

Sincerely,

Thomas Head

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Walmart
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This email and any files transmitted with it are confidential and intended solely for the individual or entity to whom they are addressed. If you have received this email in error destroy it immediately.

***** Walmart Confidential *****

ChildRule
Richard Grady
Washington Physicians for Social Responsibility
richlaura3@comcast.net

20

The value of this rule cannot be overstated. Emerging scientific data from wildlife studies and laboratory studies shows that many chemicals can and do operate synergistically. There is no reason to believe that humans are being affected differently.

none

none

none

none

none

db

12/31/2010 12:24

SUBMITTED BY WEB FORM

Submittal by web form -

ChildRule
Allen Rickert

Top Ten Toys<comma> Inc.
toptentoys@msn.com

70

At some point in the future there will be a need to address toxicity due to the synergy of chemicals<comma> but one thing at a time and should be a federal issue not state

100

100-2b I am a small retailer. I have my store name currently on things ranging from kazoos to coloring books. Under this rule will I be liable for reporting on them if the manufacturer already reports on them because I added my store name? Reduction in naming will reduce store branding and further erode my competitive ability with bigger businesses.

100-2c Like many other small toy stores<comma> I get some toys from other countries. Some other small stores have gone to the Nuremberg or Hong Kong toy shows (Nuremberg is the largest followed by Hong Kong and New York) I<apostrophe>m guessing nobody in small business will do that again but there are some of us that still get product ordered<comma> paid for and received straight from Canada with no sales rep or intermediary distributer in between<comma> like the cooperative games I get from Toronto. Legally the products are not mine until UPS drops them off at my door but it sounds like I would still be liable for testing them<comma> not the manufacturer? More product I can<apostrophe>t economically carry because of testing cost? I<apostrophe>m assuming it wouldn<apostrophe>t be worth it to the company to test if I am the only store carrying their games in the state? The sales reps I buy from also want to know<comma> if they are paid a retainer but told they are tax classified an â€œindependent contractorâ€ by their out of country manufacturer<comma> who is liable for reporting<comma> them or the manufacturer ? Many don<apostrophe>t get retainers but are commission sales for the manufacturers<comma> are they liable for reporting or the manufacturer? Washington state has many of these â€œsales reps.â€
As you can see the reporting rule is still not clear to us.
I keep hearing that nobody has to test<comma> it<apostrophe>s just reporting<comma> but with most toys made over seas now they pretty much do have to test and saying they don<apostrophe>t is a bit silly.

120

 442

120-5 - I think it is smart to use the safer alternatives assessment option to allow them an extension of a year to report and hope it will allow them the incentive to skip reporting if they have indeed found a safer alternative.

120-1 The report seems to also imply that businesses ought to be pretty darn grateful that reporting doesn<apostrophe>t apply to everyone right away and for every product type. From a small business perspective it is certainly appreciated that the rule is first enforced for the larger manufacturers and the most accessible product tiers but as the Small Business Economic Impact Statement clearly states<comma> the rule will inevitably have â€œa disproportionate impact on small businessâ€□ that lacks the â€œeconomy of scaleâ€□ to economically test products<comma> staff to report on the products<comma> staff to comprehend the rule and<comma> incredible but very true<comma> staff to even be aware the rule exists.
 Section 5 of the report makes the point but misses it. Over 99 percent of the small business affected by the rule still aren<apostrophe>t aware of the rule and those that were aware had little time to seriously study the issue and respond. We don<apostrophe>t work for the state or university. Even the Governor only has to get elected every few years.
We have to be elected every day with the voting dollars of the public or we don<apostrophe>t exist. Most of us do work more than five days a week. In the fall I work seven. When I asked manufacturers who would volunteer to pay for extra chemical testing as part of a pilot test project I was not the slightest bit surprised by the zero response.
It felt like a set up to claim you tried to consult small business but nobody responded and I wouldn<apostrophe>t have either if you hadn<apostrophe>t given the extension to Jan 7th beyond the Christmas Season. The difficulties of small business are still not heard/understood although they have been voiced before.

In the ecology of small business commerce most children<apostrophe>s products exist in stores because either they are in locations too rural for large stores to service or because they have unique products larger stores do not carry because: 1) They are produced by manufacturers too small to produce in the quantities larger stores need. 2) The wholesale cost to purchase better quality or more complex toys may not allow larger stores to price low enough to turn(sell) some toys quickly enough to justify the display space needed<comma> ultimately for their shareholder profit needs and for the large number of consumers wanting children<apostrophe>s products at the lowest possible prices.
3) They carry toys or children<apostrophe>s products unsuited for mass market appeal because they target locally made products<comma> local theme products<comma> teachers<comma> more educational products for a multitude of museum shops<comma> parks shops<comma> zoos<comma> aquariums<comma> special needs for developmentally challenged or particularly bright children or to fulfill business missions that aren<apostrophe>t simply commercial such as Math and Stuff in Seattle to promote math learning<comma> the Amphibian shop in Edmonds<comma> Wind up Here<comma> Teaching Toys and Books<comma> Top Ten Toys to promote science<comma> engineering<comma> and creative thinking. There are also specialized children<apostrophe>s furniture stores<comma> book stores.

Both the small business commercial retail and nonprofit stores rely in this business system on the ability to offer the consumer products they can<apostrophe>t get in the larger stores.
Just about everyone carries toys that are unique to them or carried by few other stores.
Therefore the small stores order small volumes of a very large variety of toys from
the small manufacturers that are too little to justify paying more for testing beyond the standard national tests. The profit margins are really that thin.

So the essence of my small business concern as it has been from the beginning is that any â€œWashington State onlyâ€□ children<apostrophe>s product safety requirements will thwart the ability of small business to acquire the products it needs to differentiate itself from the larger merchants. Even if the small

 442

business attempted to sell the same products as the mass merchants the minimum orders required by Hasbro<comma> and other mass market manufacturers is so huge<comma> only two or three could afford it. Even then they would get higher costs than the huge buyers who can get better prices with even bigger volume orders like the one who bought so many of some of one of my manufacturers puzzles this year a such low price they could retail them below my cost. You take away the competitive advantage<comma> you will hurt or take away the businesses and yes that will cause job loss and yes it will hurt kids and education and the quality of life in this state and it will make sad fun indeed of the Small Business Impact Statement and Cost benefit Analyses.
 Are you aware that just the prospect of this legislation in 2008 caused four small manufactures in this state to cease business without even bothering to test because they had reached the tipping point of their ability to cope with yet one more piece non sales related paperwork and cost. I used to incubate/test market 3-4 new toy manufacturers a year in my store some which grew to national prominence. In 2009 I only introduced one: Maxes Mud(think organic play dough) and the woman said if she had known the testing hoops she would have to go through she wouldn<apostrophe>t have done it. In 2010 nobody introduced any new toys manufactured in this state in my store. It is an unfortunate side effect of even the national legislation that toy innovation by small entrepreneurs<comma> usually teachers or therapists near my store<comma> has ground to a complete halt. They come in with ideas and samples and I try to be encouraging but when you are not making any money on the product yet<comma> the prospect of an expensive phthalate and other test or more just kills the idea. They most definitely don<apostrophe>t have a list of their component part ingredients. I suppose additional Washington only requirements only nails that coffin but I wanted to make it clear that jobs have already been lost and others not created by the current testing requirements without even yet being exacerbated by more tests just for our state.

In 08 people justified the Washington state only Children<apostrophe>s Product legislation because they claimed the federal government wouldn<apostrophe>t act to create national protection on lead and phthalates but the federal government did! In December of 2009 the federal EPA invoked the Toxic substance Control Act of 76 announcing it<apostrophe>s attentions to create and address â€œChemicals of Concernâ€ and push for new uniform U.S. regulations to investigate and control chemicals of concern and has continued that work in 2010. So why are we risking small or any other business in Washington State with a fast track non delayed rule to once again push for testing unique to our state when the federal government is on that path with one of the leading legislators on toy safety now the President of the United States?

140

140- It seems kind of odd to ask manufacturers to report on some chemicals that are already outright banned in toys under ASTM and other groups. Redundant?
none

none

db

1/7/2011 22:18

The Procter & Gamble Co.
Facsimile Cover Page
1 Procter & Gamble Plaza
Cincinnati, OH 45202

North America Legislative & Regulatory Affairs
Phone: (513) 983-0530 Fax: (513) 983-8984

DATE: January 7, 2011

Subject: Children's Safe Products Act

To: John Williams Company: WA DOE	Fax #: 360-407-6102 Phone:
To: Company:	Fax #: Phone:
From: Chris Guay Company: Procter & Gamble	Fax #: 513-983-8984 Phone: 513-983-0530 Email: (guay.cb@pg.com)

Pages including this cover page: 5 + Cov

John:

Attached are comments.

THX

Chris Guay

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One Procter & Gamble Plaza (C-6)
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January 7, 2011

Mr. John R Williams, Jr.
Waste 2 Resources
Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600

Re: Children's Safe Products Reporting Rule (October 22, 2010)
Public Comment Period

Dear Mr. Williams:

The Procter & Gamble Company (P&G)[1] appreciates the opportunity to comment on the Department of Ecology's (DOE) proposed regulation (WAC 173-334) to implement the Children's Safe Products Act (RCW 70.240). P&G supports the need for ensuring that all consumer products are safe.

P&G requests that DOE provide important clarifications regarding the scope of the Childrens Safe Products Act in its final regulation. We believe these are necessary since the basic definitions in the Act are somewhat confusing and in need of interpretation.

Food and Drug Products should not be considered Children's Products.
Section 1(3)(a) of the Children's Safe Products Act defines "children's product" to include toys, children's cosmetics and jewelry, child car seats, and products "designed or intended by the manufacturer to help a child with sucking or teething, to facilitate sleep, relaxation, or the feeding of a child, or to be worn as clothing by children". A number of products subsequently are excluded from this definition. Interestingly, the definition of "cosmetics" in Section 1(4) specifically excludes food or drugs approved by the United States Food and Drug Administration (FDA). This leaves the status of food and drugs uncertain -- they are not cosmetics but they still appear to be viewed as children's products, regardless of the manufacturer not having that intention. Since it is unclear whether the exclusion contained in the definition of cosmetics was meant to exclude food and drugs generally, it would be very useful for the DOE to provide clarification on this question in its new rules.

[1] The Procter & Gamble Company is the world's leading consumer products company operating in more than 80 countries worldwide. Our strong portfolio of recognized, quality and leadership brands includes numerous household, industrial and personal care products. Procter & Gamble is fully committed to helping solve sustainability challenges, which is embedded in our Company Purpose "to improve the lives of the world's consumers, now and for generations to come." Please visit http://www.pg.com for the latest news and in-depth information about P&G and its brands.

From a practical standpoint, it is our belief that food and drug products should not be considered children's products. Both food and drugs are broadly used by the entire population and they are regulated by the FDA as well as state regulators. Trying to separate these classes of products in order to identify products used by those age 12 or under will necessarily capture the full spectrum of food and most drug products. This would be an incredibly large, unwieldy classification and would certainly strain both public and private sector resources to comply. As a result, we recommend that DOE provide clarification that this Act (and its implementing regulations) does not consider foods and drugs as children's products.

A Combination Drug/Cosmetic Product should not be considered a Children's Product.
A large number of OTC (over the counter) drug products are regulated as both drugs and cosmetics by the FDA. These products are primarily drug products, but their "dual action" nature and form also provide attributes which FDA regulates as cosmetic. For example, dandruff shampoo is a drug based on its anti-dandruff action but it is also a cosmetic since it cleans and beautifies hair. Anti-cavity toothpaste is also a cosmetic since it helps clean teeth and freshen breath. Similar drug and cosmetic benefits occur with OTC products such as sunscreens, mouthrinses, and antiperspirants.

We recommend that products regulated by FDA that are both OTC drugs and cosmetics not be considered children's products under the Washington statute based on the fact that they are primarily drug products. Again, clarification on this question by rule would be extremely helpful.

Medical Device Products should be considered similarly to Drug Products.
A large category of products regulated by FDA that is not recognized or discussed by the Act is medical devices. A medical device is defined within the Food Drug & Cosmetic Act as "...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." Like drugs, FDA has an extensive regulatory structure for regulating medical devices. We recommend that DOE consider clarification regarding the status of medical devices in a manner consistent with drug products and not provide a rule definition with an overbroad and unintended scope.

Manufacturer's intent based upon a preponderance of information regarding product type, labeling, promotion and advertising should be the primary determinant regarding what is not a children's cosmetic product.
The Act defines a children's cosmetic to mean "cosmetics that are made for, marketed for use by, or marketed to children under the age of twelve." We support this definition to the extent it recognizes that a manufacturer's primary intent should be the determining factor. However, we believe the Act goes further to define conditions which do not provide sufficient context for making clear determinations regarding what is, or is not, a children's cosmetic product:

RCW 70.240.010(1):

"Children's cosmetics" includes cosmetics that meet any of the following conditions:
(a) Represented in its packaging, display, or advertising as appropriate for use by children;
(b) Sold in conjunction with, attached to, or packaged together with other products that are packaged, displayed, or advertised as appropriate for use by children; or
(c) Sold in any of the following:
(i) Retail store, catalogue, or online web site, in which a person exclusively offers for sale products that are packaged, displayed, or advertised as appropriate for use by children; or
(ii) A discrete portion of a retail store, catalogue, or online web site, in which a person offers for sale products that are packaged, displayed, or advertised as appropriate for use by children.

Whereas the definition seems to potentially provide a reasonable standard regarding what is and is not a children's cosmetic, stating that "any of the following conditions makes a product a children's cosmetic" has the potential to render almost every cosmetic product a children's cosmetic product.

In the past 10-15 years, various state, national and international agencies and organizations have asked manufacturers to include product usage instructions for non-adults who might be using products or for parents choosing to use a product for their child. As a result, products which a manufacturer intends to be used by adults or older teens may have directions for use for 8-12 year olds or 10-12 year olds. For such situations, we recommend that DOE provide that a cosmetic product needs to have either a preponderance of or a significant proportion of advertising, labeling, and product information indicating that it is intended for use by children – not merely a single or isolated reference. Absent guidance from DOE, manufacturers may simply choose to remove the directions for use for these younger age groups and/or state "not for use by children" in order to more clearly ensure their products intended for older youth and adults are not interpreted to be children's products. This will result in there being less instruction and information available when a person under 13 may choose or need to use a product, which we believe is counter to the consumer's best interests.

Shelving decisions are at the sole discretion of a retailer and manufacturers cannot and should not decide where their products are sold. For example, if a major chain store in Washington state chooses to sell make-up adjacent to the toy section of its store, does that display choice turn make-up into a "children's product" under the statute or draft rules? To what extent are manufacturers obligated to monitor and track what retailers choose to do with our brand names in their stores? We suggest that manufacturer's intent based on labeling, advertising and promotion is a more meaningful and logical standard.

Consistent with the comments above, we recommend the following revisions to the draft regulations in providing added clarity to the regulated community and other stakeholders.

WAC 173-334-040 What definitions apply to terms used in this chapter?

"Chemical Abstracts Service number" means the number assigned for identification of a particular chemical by the Chemical Abstracts Service, a service of the American Chemical Society that indexes and compiles abstracts of worldwide chemical literature called *Chemical Abstracts*.

"CHCC list" means the reporting list of chemicals that the department has identified as high priority chemicals of high concern for children.

"Child" means an individual under twelve.

"Department of health" means the Washington state department of health.

"Exempt products" means those products specified in RCW 70.240.010(3)(b), products regulated as food by either the United States Food and Drug Administration or the United States Department of Agriculture, products regulated as prescription or over-the-counter drug products regulated by the United States Food and Drug Administration, products regulated as medical devices by the United States Food and Drug Administration, and products regulated as both a drug and a cosmetic by the United States Food and Drug Administration.

"Manufacturer product intent" means, through an objective evaluation, the target age range intended for use or consumption of a product, as demonstrated by product design, protocol, testing, labeling or advertising.

"Product category." For those products ***defined by the manufacturer's product intent to be*** for children three years of age and under, product category means the "brick" level of the GS1 Global Product Classification (GPC) standard, which identifies products that serve a common purpose, are of a similar form and material, and share the same set of category attributes. For all other children's products, product category means the "class" level within the hierarchy of GS1 Global Product Classification (GPC) standard.

"Product component" means a uniquely identifiable piece, substrate, or coating (including ink or dye) that ***a manufacturer intends to include*** as a part of a finished children's product.

WAC 173-334-090 What must the manufacturer include in its notice to the department?

(1) The notice required by RCW 70.240.040 must be filed annually with the department for each CHCC ***by product category and component for children's products as defined in WAC 173-334-040.*** The notice must include all of the following information:

(a) The name of the CHCC and its Chemical Abstracts Service registry number.

(b) The product category or categories in which it occurs.

(c) The product component or components within each product category in which it occurs.

(d) A brief description of the function, if any, of the CHCC in each product component within each product category.

(e) The total amount of the CHCC by weight contained in each product component within each product category. The amount may be reported in ranges, rather than the exact amount. If there are multiple CHCC values for a given component in a particular product category, the manufacturer must use the largest value for reporting.

(2) Reporting parties are not required to include either:

(a) Any information pertaining to exempted products; or

(b) Any specific formula information; or

(c) The specific name and address of the facility which is responsible for the introduction of a CHCC into a children's product or a product component.

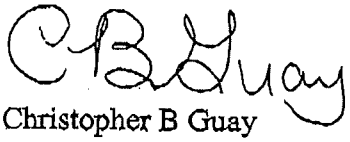
WAC 173-334-100 Who is required to provide notice to the department?

(1) The manufacturer of a children's product as defined in RCW 70.240.010, ***and as further determined by manufacturer product intent***, or a trade organization on behalf of its member manufacturers, must provide notice to the department that the manufacturer's children's product component contains a chemical on the CHCC list.

(2) The definition of manufacturer in RCW 70.240.010 includes any person or entity that produces a children's product, any importer that assumes ownership of a children's product, and any domestic distributor of a children's product. However, it is only necessary for one person or entity to provide notice with respect to a particular children's product.

The Procter & Gamble Company appreciates the opportunity to comment on this proposed regulation. Should you have any questions about these comments, please contact me at (513) 983-0530 or guay.cb@pg.com

Sincerely,



Christopher B Guay
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CSPA Reporting Rule Hearing

December 9, 2010

This evening we are conducting a hearing on the proposed Children's Safe Product Reporting Rule. Let the record show it is 7:41 on December 9th 2010, and this hearing is being held at Ecology's Headquarters and Southwest Region Office, 300 Desmond Way SE in Lacey. Legal notices of this hearing were published in the Washington State Register October 22, 2010, Washington State Register No. 10-22-017. In addition, notices of the hearing were sent by list serve to approximately 250 interested people, the Toy Industry Association, Association of Washington Businesses, Personal Care Products Council, American Apparel and Footwear Association, Washington Retailers Association and a news release was issued on October 22, 2010. I will call people up to provide oral testimony based on the order I received your sign in cards. Once everyone has indicated they would like to testify, has had the opportunity, I will open it up to formal testimony by others. We have 11 people signed up to provide formal testimony. Remember comments should be about 5 minutes. I will give you a reminder when you have one minute remaining. When you reach 5 minutes, I will ask you to summarize, when you reach the one minute mark, I will ask you to summarize your comments so the next person can come up and testify.

When I call your name, please step to the front. State your name and address for the record, and speak clearly so we can get a good recording of your testimony. We will begin with Chris Guay and to be followed by Evan Hirsch.

Please remember to state your name and address for the record.

My name is Chris Guay. I am from the Proctor and Gamble Company in Cincinnati, Ohio. Angie and John, thank you for holding this tonight. I am here just to ask for clarification on the scope of the act in terms of how, what products were considered in scope and out of scope of this. In particular, the question is, "What is a Children's Product and what is not?" Ideally, we would like to see it based on the intent of the product based on looking at that but would the age range being from 0-12, a lot of adult products were potentially used by 11 and 12 year old people and the question we'd like clarified is that if the intent is really for the product to be used by older teenagers and adults to get something in there which clarifies that that is not a children's product. For example, make up would be used by adults however with young ladies, they may want to even at 10, 11, and 12 potentially start using it and why it's intended and marketed to adults, you know it may be used by that sub group and we'd like to get clarification of the intent of the rules, products that are intended clearly for that age group as opposed to products that might be used as they try to look ahead to becoming and looking older. In addition to that, I'd like clarification on other products whether they're in scope or not because of how they're regulated. For example, there are over the counter drug products such as sunscreens and toothpaste which are both OTC drugs in cosmetics and the question is, "Is that make me note, they're in scope because they have, part of it considered a cosmetic or are they out of scope because the main part of

the product is a drug?" That's important because, FDA is wanting OTC drugs to include instructions for use for younger sub populations and therefore some of these products may have a statement on it for instructions for use by a younger group and that's because of FDA wanting that there. The question is whether that is again the intent of the act be covered by this considering that they are primarily OTC drugs and those instructions are for their drug uses. Finally, the question is dealing with other scopes of products that are regulated. For example, medical devices, foods, dietary supplements. Again, all regulated by FDA, they're not cosmetic products, obviously, all can or may be used by children, the question is whether they are in scope or out of scope based on the law and the intent of what you want to do. And then finally, a curious situation's, a product like soap. Soap is a cosmetic only if someone claims something like moisturizing skin. If they just talk about it for cleaning, it is not. So the question is for a product like that, do you want that to be considered in scope or out of scope realizing that some products in that category are not going to fit the definition and other ones are going to fit the definition of a cosmetics product and therefore it should be subject strictly on the claims whether they are or not in scope. Thank you.

We will now have Evan Hirsch followed by Sophia Aragon.

I apologize for my handwriting. I think that's probably Hirsch. Let's just double check. Yeah, sorry. I'll spell that, Evan Hirsch. Address: 1326 9th Ave SE Olympia, Washington 98501. Hello, my name is Evan Hirsch; I'm a family doctor with a practice here in Olympia and the father of a 2 ½ year old. I am trained in Environmental Medicine and I'm the Medical Director of the Providence Integrative Cancer Care Program. I want to thank you for moving forward with this rule. I would also like to make some recommendations today on how I believe it could be improved. First, I would like greater access to the information concerning the toxins present in the product components. My patients want to protect their families from toxic chemicals. As their doctor I'm able to give them guidance. But more information is needed to help them choose the safest children's products. When my daughter was born my wife and I searched for non toxic products with which she would play, eat, drink and sleep. Our search was challenging since this information was not readily available in one place from a more reliable and trustworthy source. This reporting rule is a good first step to take action on products that pose a threat to our children's health. However, access to this critical information is necessary in order to make educated product decisions. Please include a plan in the final rule to ensure that the public has easy access to this information, possibly in the form of a website or a readily accessible database. Second, I believe the rule should require companies to report any detectable amount of toxic chemicals, not just above 40 parts per million. Many chemicals are harmful even in very small quantities. Toxicity is often due less to the dose, and more to the timing and repeat exposures. It is also due to the individual's ability to detoxify as I spoke with John previously. I have children in my practice who have problems with liver detoxification. This means that their tolerance to different chemicals is less and even small exposures can cause symptoms and illness. For these children, transparency will allow their parents to assist them in avoiding toxins in their environments. I refer to these patients as our canaries in the coal mine for they are the harbingers of what is to come if we do not regulate environmental toxins. To be clear, these children are not the anomaly. The statistics suggests that 40 to 60% of all person's have some issue with liver detoxification specifically with these two detoxification methodlation. Requiring

companies to report chemicals at detectable levels will provide important information we need to truly protect children from harmful yet nuanced exposures. Finally, I believe that the rule should require manufacturers to indicate in which product the chemical is being used versus product categories or product components. This layer of information communicates which individual products have the highest toxicity and this is the level of detail that consumers deserve on a more practical level when they're actually choosing the toy or the product. Thank you again for your time and care you've put into this process. I am proud to be living in a state that is taking its duty to protect its most vulnerable residents, our children, seriously. Thank you.

We will now have Sophia Aragon followed by Steve Brough.

Good evening, I'm Sophia Aragon with the Washington State Nurses Association and we're located at 575 Andover Park West Suite 101 in Seattle, Washington. Thank you for moving forward with this rule. It's an important component in protecting children's health from toxic chemicals in consumer products. The Children's Safe Product Act or CSPA was passed in response to a very real problem. Harmful chemicals in products that children play, eat and sleep with everyday. Parent' s have no way of knowing whether the toy they give to their children could make them sick and government regulators do not have enough information about the chemicals in products to know whether a problem exists and action should be taken. One of the biggest barriers in regulating harmful chemicals in consumer products is a lack of information about the chemicals present in everyday items. The CSPA Reporting rule will help close the information gap. The list and reporting requirements are a good first step in a country where government agencies charged with keeping us safe don't even know what's in toys and other consumer products. Government agencies too will get information they need to take action on those products that pose a threat to children's health. To protect children's health and the environment, the rule should been proved, our recommendation are three things. First, require the companies to report lower limits for chemicals. Some chemicals are toxic in very small amounts so companies should have to report even these small quantities. Secondly, require companies to report when and where they're using a toxic chemical and finally, Ecology should also include a plan on how they will ensure the public has wide and easy access to the information on these chemicals. Thank you very much for your hard work in this rule and please put children's health first. Thank you.

Steve Brough followed by Edward Cates.

Good evening, my name is Steve Brough and I'm a Public Interest Advocate for WashPIRG, the Washington Public Interest Research Group. We're located at 1402 3rd Avenue Suite 715 in Seattle, Washington. WashPIRG is a non-profit, non-partisan group that seeks to protect consumers, encourage a fair and sustainable economy and foster response of democratic government. As a member of the Toxic Free Legacy Coalition, WashPIRG is very concerned about the need to ensure that the products that children play and sleep with are free from harmful chemicals. Although Children's Product Safety has come a long way in the last generation, there is still serious issues that need to be addressed. WashPIRG recently released our 25th Annual Trouble in Toyland Toy Safety Report, which outlines the hazards that exists among toys on store shelves today. And the most common problem identified in this year's report was the presence of toxic chemicals such as lead, antimony and thialates in children's toys.

The Children's Safe Products Act was passed in response to a very real problem. Harmful chemicals in products children play, eat and sleep with everyday. It's bad enough that parents have no way of knowing whether the toy they give their child can make them sick but before we could address that problem, we need to make sure that government regulators have enough information about these chemicals to know whether a problem exists and if action should be taken. One of the biggest barriers in regulating harmful chemicals in consumer products is the lack of information about the chemicals present in everyday items. The CSPA Reporting Rule will help close that information gap. A comprehensive list and more stringent reporting requirements are a good first step to ensuring that government agencies have the information they need to take appropriate actions on those products that pose a threat to children's health. To protect children's health and the environment, we would encourage that the rule be improved to do the following. One; because some chemicals are toxic in very small amounts, companies should have to report when even small quantities are present. Two; require companies to report how many product or components in a product category contain that toxic chemical so that the agency knows the extent to which the chemical is used. Three; the Department of Ecology should develop a plan on how they will ensure that the public has wide and easy access to the information on these chemicals. Thank you for your hard work on this rule.

Edward Cates followed by Andy Hackman.

Hi, my name is Edward Cates and I'm a family physician in Olympia, Washington and I thank you for the opportunity to provide public comment on the Children's Health and Product Safety, Safe Product Act Reporting Rule. So I'm speaking to you today as both a father of two boys age 6 and 12 and as a family physician. As we all know, children are uniquely vulnerable to toxic chemicals. Their brains and their bodies are developing rapidly and development is easily disrupted by toxic chemicals. Pound for pound they're exposed to more toxic chemicals than adults as anyone knows seeing children crawl around on the floor and putting all matter of things including their hands and toys in their mouth as you stated during your presentation. Everyone knows that keeping children healthy is no easy matter. If I could, I would prescribe toxic free products to make sure that children have the best and safest start possible. Unfortunately, we have no way, currently of knowing whether a toy or any item kids use contain chemicals that are harmful to their health. As a doctor, I wish I had the ability to provide this information to my patients to protect their families from toxic exposures. As a father, I also know how much stress and uncertainty is put on parents trying to protect our kids. It often feels like we're on the front lines alone fighting in a dark room with the burden of proof resting on our shoulders. We simply don't have the information we need to make healthy choices. That's why I'm so glad that you're moving forward with this rule. The Children's Safety Product Act Reporting Rule will help fill in the missing information that we need. This rule is a great first step to help get parents, health care providers, and government agencies the information they need to keep our children safe. I applaud your efforts and would like to make the following suggestions to improve the rule. Firstly, I would like to require companies to report whenever a chemical is present in the products. Some chemicals are toxic in various small amounts and we need to have the information when and where they're used or wind up in the product as a result of manufacturing products, the manufacturing process, sorry. Also, I think that we should require companies report when and in which specific products toxic chemicals are used so that parents and

health care provides can know which specific products to avoid and in that way, I feel like the category criteria is inadequate to allow people to make specific choices and lastly to ensure that the public has wide and easy access to the information on chemicals so that we can use the information to start making healthier choices for our children. Lastly, I'd like to thank you for hearing my comments on this rule and also I appreciate all the hard work that obviously goes into making an effective rule and learning this process. Thank you.

Andy Hackman followed by Tom Lowendowski.

Good evening, my name is Andy Hackman. I'm here on behalf of the Toy Industry Association. We are based in New York City, NY, and I appreciate the opportunity to provide comment tonight. The Toy Industry Association represents over 550 members that manufacture and distribute toys here in the United States. We have appreciated the opportunity to work with the department on development of this rule; we appreciate the stake holder's process and the progress that has been made on many key issues in terms of enhancing information and data that's provided to consumers. Safety is our number one priority. As a father myself of a two year old daughter, we want to ensure that consumers understand and are informed of the materials that are used in toys and children's products. We appreciate that this rule has worked to address those exposures of most concern and we believe the issue of exposure should continue to be an overlying factor within this regulation. Specific to the trigger levels and the reporting as they occur under the rule, we question the department as to why 40 parts per million has been chosen as the initial trigger level. We suggest that the department improve the rule, make it consistent with the European Reach Chemicals Regulation in Article 7 that stipulates that the trigger level be 1000 parts per million for articles. This level's also specified in the California Green Chemist Regulations that are under consideration in California. This trigger level will provide uniformity across international jurisdictions; it's been shown to be acceptable in other jurisdictions for chemical regulations impacting children's products and consumer products in general. We also suggest that the department evaluate whether or not the trigger levels should be set for the total product and the total exposure. We believe the focus of this rule should be on exposing the greatest concern and we believe that the trigger levels should be specified to the total exposure to a product. We also reference the European Reach Regulations in reference to evaluating exposure from the total product. Current Reach guidance directs the states to evaluate a product based upon how it is produced or imported; the final product. We urge the department to consider reasonable, foreseeable use of the product in terms of exposure and evaluating those exposures of greatest concern. We also urge the department to consider the inclusion of intentionally added ingredients as referencing the department's Phase 3 Report, we believe intentionally added ingredients should be the focus of these regulations and should be specifically called out in the rule. We also believe that the chemicals listed in the report, in the requirements for reporting should be justified or documented specifically as to how they were selected beyond the fact that they meet the criteria in legislation. As understood, thousands of chemicals could meet the criteria stipulated in the statute. We need to understand specifically how the data indicated that these 59 chemicals were pulled out instead of other chemicals. Again we appreciate the opportunity to work with the department. We appreciate the tiering in terms of reporting and look forward to creating a rule that's workable and protective of children's health.

Tom Lowendowski followed by Erica Schredder.

Hello, my name is Tom Lowendowski. I'm a toxicologist with Gradient, a consulting company based in Seattle, Washington. Our address is 600 Steward Street, Seattle, Washington 98101. I work primarily in the areas of consumer product safety and green chemistry. I wanted to first congratulate the Department of Ecology and all the stakeholders on what I think is a very thorough and careful effort to address this very important topic. I do have three specific comments though on the regulation. First of all, I do appreciate the statement that's in the current regulations; the effect that hazard is not the same thing as risk. However, presumably the majority of the information collected under this regulation will not be confidential business information or CBI and will therefore be subject to a flare request as part of the Washington Open Records Act. I think it's an inevitable that the collected information will get out there via the internet and inevitably become present on some sort of website where it's mentioned that one product is good and one product is bad simply because they contain a certain chemical without really looking at the potential risk. Therefore, I think, actually a number of individuals have already commented that many chemicals are very toxic and even at very small doses and therefore they're I think equating the fact that just the mere presence of a chemical is resulting in a risk when in fact you really need to consider both risk potency and exposure. Therefore, I was curious to know whether Ecology has any plans to provide context for this sort of information along with anything that they may release in terms of chemical concentrations. Perhaps Ecology will develop their own website similar to what's being done in California under the proposed Green Chemist Regulations that would at least put you in the driver's seat and allow you to provide the information with some sort of context which I think would be appropriate. It's also true that under Section 90 of the regulations there is an allowance for companies to provide any additional information they think appropriate to address their product and so that may be another way that Ecology could maybe structure certain exposure codes or something that would allow companies to say how that chemical is actually present in their product. Another thing I want to comment was the Tier 4 categories. I appreciate that exposure is actually being considered in that particular category but I think the regulations could require, could involve some additional clarification as to what manufacturers who have Tier 4 products must do proactively to avoid any sort of penalty. I think that's not particularly clear at this time. And then lastly, as far as the list of chemicals, I would request that Ecology stipulate the basis for each of those chemicals being put on the list in the regulation itself, to make it sort of clear to those who are reviewing the regulations and the list why certain chemicals are listed. I find that's actually particularly helpful with for example the Prop 65 list in California to know some of the basis and just one or two key words. I think that would be very helpful. Thank you. I can leave you my scratches if you want.

O.k., Erica Shredder followed by Laura Hart.

Good evening and thanks for the opportunity to testify today. My name is Erica Shredder and I'm a staff scientist with Washington Toxics Coalition and we're located at 4649 Sunnyside Ave North Seattle, 98146 excuse me 98103. We'd like to thank the Department of Ecology for moving forward with this really important rule that will help fill critical data gaps on the use of harmful chemicals in toys and other children's products. It's clear from ongoing reports that the use of toxic chemicals in children's products is still prevalent and many are not adequately regulated by Federal Law. Just as one example,

that just this summer, more than 10 million Shrek glasses from McDonalds were recalled voluntarily after cadmium was found and following the recall, the Federal Government decided still not to have mandatory limits for cadmium, they're still voluntary. In addition to the critical information the rule will provide, we believe it'll help manufacturers in their quest for safe products. We know that many companies are trying to do the right thing and to get information from suppliers on the toxic content of their products, but this has been a challenge for those companies. With this new rule, more information will flow in the supply chain, creating more opportunity for better material and product choices. We have specific comments on the rule regarding the chemical list, reporting thresholds, getting more information on the extent to which chemicals are used, and ensuring wide public access to the information that's gathered. So first of all, the chemical list. Overall, we think that Ecology really captured many chemicals that are of high concern for children. The methodology for the inclusion of this chemical is really strong and we appreciate the process by which it was developed. We do have several concerns. First lead and certain thaliates have been kept off of the list and consumers , you need to be concerned about the presence of these chemicals in children's products because for lead the federal limits are quite high, 300 parts per million and under the Federal Statute, only a few thaliates are prohibited. So we don't believe that the federal law preempts the agency from taking action to collect information on these chemicals. Finally, the agency did not specifically address, one of the priority categories for toxicity neurotoxicity, but that was in the law so we ask that these chemicals be prioritized when the agency updates the list in the future rule making. Second, the reporting threshold levels. Ecology really has the right approach in this role with respect to the reporting threshold level. The disclosure part of the law was not intended to establish safe levels of chemicals in products rather it was designed to provide consumers and the government with more information. But while the approach is correct, we're concerned that the 40 parts per million reporting trigger value is too high to capture certain chemicals. For example, according to previous published studies, at 40 parts per million minimum would miss formaldehyde in baby mittens, styrene and toluene in baby jackets and N-nitrosodimethylamine in pacifiers and nipples. These are chemicals that Ecology has ranked as carcinogens, developmental and reproductive toxicants but they're present in these products at levels below 40 parts per million. So to capture these and other chemicals, we believe that reporting should be based on level of detection. So in other words, any amount above detection limits should be reported and to make sure that this isn't too onerous for manufacturers, we would consider language that makes it clear that this detection limit reporting applies only when chemicals are intentionally added, used in manufacturing of the product or known process contaminants. Setting the reporting limits, reporting requirements based on detection limits will ensure clear requirement and not create questions on whether the level is protective, too protective or not protective enough. Third, your requirements for disclosing numbers of products containing a given chemical. The law was very clear that manufacturers need to provide the chemical data for each product unit. The law clearly states that the manufacturer must report "the amount of the chemical used in each unit of the product or the product component". The current rule draft doesn't contain that information or doesn't ensure that information on each product that contains the chemical is obtained because it allows reporting by product category. This might ease implementation but we're concerned that a large data gap will persist which is to what extent is that chemical used. For example, if manufacturers simply reported that the specific chemical, or excuse me, if manufacturers reported the specific chemicals contained in baby doll X, we'd be able to

figure out how wide spread the exposure is based on the popularity of that particular product but if we only know it's used in baby dolls it doesn't tell us much about the extent of the chemical's use. If the agency isn't going to follow the letter of the law and require data on each product then, at a minimum, it should require manufactures to disclose how many product units approximately the chemical was used in. That would allow the Department of Health to provide more accurate information to consumers on the chemicals in products which is also required by the law and it will give useful information to Ecology on what product categories should be prioritized for the development of safer alternatives. And then finally, public access to the information. The intent of the law was to provide the information to the public via the website, via the web, and specific language in the bill to that effect was passed by the legislature. The rule states the manufacturers must use a web form and we would like the rule to specifically state that Ecology would make this information publically available on the website or at minimum we would like Ecology to come up with a plan for how this information will be published on the web and distributed to the public. I did it, again, thank you very much for proceeding with this rule; appreciate your work on it. Let's see, this is a clean copy for you; it's not marked up by me.

Laura Hart followed by Anna Dyer for Jen Allen.

Hi, thank you for this opportunity to testify. My name is Laura Hart. I'm here on behalf of the organization, Washington Physicians for Social Responsibility at 1604 NE 50th Street in Seattle. I'm also here as an individual urologist and unlike my colleagues Dr. Evan and Dr. Eddy; I don't have the opportunity to do as much preventive care as opportunities to see patients who come to me with a problem. We pay the price for toxic chemicals in children's products in increased health care cost and in the compromised health of Washington's children. Toxic chemicals have been linked to a variety of chronic diseases affecting children that are currently on the rise including asthma, cancer, birth defects and neuro-behavioral effects. The Centers for Disease Control, estimates that 133 million Americans live with chronic conditions like cancer, asthma and infertility. These problems account for 75% of US health care costs not to mention the incalculable cost of human pain and suffering. The 2005 study estimated the annual cost of childhood diseases and disabilities attributed to toxic chemicals in Washington State alone is about $310.6 million dollars in direct health care costs and $1565 million in indirect costs. In my practice as a urologist who sees both adults and children, I see three problem areas; Infertility, testes cancer, and congenital birth defects primarily in the male urinary system. So the number of little boys that I see with the condition hypospadias has increased since I have been in practice in 20 years. What we know across the board in industrialized nations, not only in the state of Washington is that the sperm counts for men are ½ of what they were in the 50's. Now I can't say that that has anything to do with the toxic soup we live in but I would suggest that if there's any role that toxins play, I'd like to see it addressed. Chemical exposure is one factor we can do something about unlike our genetic background or we can also do something about our amount of exercise and nutrition. So moving forward with the Children's Safe Product Act Rule is a great step to give health care providers and government agencies the information we need to prevent disease linked to chemical exposures and their associated costs. I would add these suggestions to improve the rule and increase the effectiveness of the information provided and given the excellent testimony provided by my predecessors, you can only imagine that I'll support the idea that we need to look at detectable levels not an arbitrary 40 parts per million and I will

include rather than repeating that in my written testimony that I'm submitting right now, I thank both of you for the time and the energy it took to create this hearing tonight. Thank you very much.

Anna Dyer followed by Garrison Dyer.

Do you want my address or (>>>), o.k. My name is Anna Dyer and I'm reading this email on behalf of Jennifer Allen and my address is 949 24th Avenue South Seattle, Washington and Jennifer Allen is the Director of Planned Parenthood Public Policy and her address is 2001 E. Madison Seattle, Washington 98122. As the nation's largest and most trusted reproductive health care provider it is our mission to promote healthy individuals, healthy families, and healthy pregnancies. We are becoming increasingly alarmed by the evidence linking toxic chemicals to health problems including infertility, breast cancer, and early onset of puberty. It is clear that we need to act now to protect public health. This rule is an important step for protecting people especially children from toxic chemicals in consumer products. Right now people have no way of knowing whether the products they're buying could make them sick. Even the toys parent's give to their children and government regulators do not have enough information about the chemicals in products to know whether a problem exists and if action should be taken. To protect public health and the environment, this rule should be improved to require companies to report lower limits for chemicals. Some chemicals are toxic in very small amounts so companies should have to report even small quantities. Require companies to report when and where they're using a toxic chemical. The majority of patients at Planned Parenthood are low income and are uninsured and have already had fewer resources to stay healthy. We need to make sure that information on toxic chemicals and products is easily accessible for everyone. We'd like to see the Department of Ecology include a plan in the rules for how they will ensure public access to this information. Thank you for the opportunity to provide comments and your hard work on the rule.

Garrison Dyer and then we'll open up the floor for anyone else who didn't sign up and would like to make comments.

My name is Garrison Dyer and my address is 949 24th Avenue South Seattle, Washington 98122. First I want to say thanks for having us here for public comment. This issue is very important to me and I'm just very glad that you've given us the opportunity to come and express our opinions. Now, I unlike some of the other commenter's am not a father but every day I do look after about 121 11-14 year olds as a science teacher at Sir Walter Middle School in Tukwila. I've grown to care immensely about my student's health, their safety and their development. In the past I've also worked in self contained special education classrooms with students who are developmentally delayed and have learning disabilities. Approximately 1 and 6 American children have a learning or developmental disability and recent research shows that this number is getting bigger. 13% of the students in my classes have been diagnosed with learning or behavioral disability and I have no idea how many others may have slipped through the cracks and are simply going to school undiagnosed. I can tell you from firsthand experience that these disabilities can take a tremendous toll on the child and the family in the classroom. Now the latest research indicates that some of these disabilities may be preventable by reducing a child's exposure to toxic chemicals. According to the US National Research Council, 3% of developmental disabilities are the direct result of exposure to toxic chemicals and another 25% result from interactions

between environmental and genetic factors. Children are exposed to chemicals from a variety of sources but those sources shouldn't include their favorite toy, their favorite cup, a teddy bear or necklace. For example, lead found in paint or PVC plastic and jewelry is linked to ADHD, reduced IQ's and juvenile delinquency. Polycarbonate plastic food containers and the linings of food cans contain v… which is linked to altered behavior and hyper activity. So I'd like to thank you for moving forward with this rule. We do need to start collecting the information that we need to protect children from unnecessary suffering and disability. With this in mind, I'd like to suggest the following improvements to the rule. First, please set the reporting limit at the level of detection of the chemical instead of the 40 parts per million. For some chemicals, 40 parts per million trigger is too high to detect levels that could harm children and we want to have all the information available to make informed choices once the data is collected. Second, please require companies to disclose how many toys or units on which the chemicals were used to help us determine the true scope of the situation and finally, please make the information you collect widely available to parents and consumers. Parents and care takers are really the first line of defense for kids and they deserve to have access to this information or any information that may make their job just a little bit easier. Thank you.

Is there anyone else who wishes to provide testimony that didn't sign up tonight?

If you would like to send Ecology written comments, please remember they are due December 31, 2010. Send them to John Williams, Waste 2 Resources Program, Department of Ecology, P.O. Box 47600 Lacey, WA 98504-7600 or to john.williams @ecy.wa.gov, or to fax, 360-407-6102. All testimony received at this hearing along with all written comments received by December 31, 2010 will be part of the official hearing record for this proposal. Ecology will send notice about the Concise Explanatory Statements publication to everyone that provided written comment or oral testimony on this rule proposal, eve3ryone that signed in today for today's hearing that provided an email address, other interested parties on the agencies mailing list for this rule. The Concise Explanatory Statement will among other things contain the agencies response to questions and issues of concern that were raised during the public comment period. If you would like to receive a copy but did not fill out a card or sign in with your email address, please see me after the hearing. The next step is adoption. Ecology Director Ted Sturdevant, will look at the public comments, the Concise Explanatory Statement, other rule documentation and staff recommendations and make a decision about adopting the proposal. Adoption is currently scheduled for spring 2011. If the proposed rule should be adopted that day and filed with the Code Reviser, it will go into effect 31 days later. If we could be of further help to you please do not hesitate to ask or you can contact John Williams if you have other questions. On behalf of the Department of Ecology, thank you for coming tonight. I appreciate your cooperation and courtesy. Let the record show the hearing is adjourned at 8:24 p.m. Thank you.

Children's Safe Product Act – Reporting Rule
Summary and Response to Public Comment on Original Rule Proposal

May 4th, 2011

Below is a summary of the comments received on the original proposed rule. Because many commenters had similar concerns about the rule, we've paraphrased the comments and listed specific commenters in parenthese, followed by our response. A list of commenters and the associated abbreviation can be found at the end of this document.

1) Mere reporting does not establish harm

We applaud the department for clarifying that this is a reporting law, and as such just reporting the presence of the chemical does not establish harm. (ACC, G, AAFA, VI)

> *Agency Response*
> We have tried to make it as clear as possible that the mere presence of one of the chemicals does not establish harm.

We are still concerned that the public might not understand this concept. (TIA, ACC, G)

> *Agency Response*
> The reporting party has the option to provide additional information when submitting a report; some may want to include clarifying information regarding this issue (e.g. risk assessments, toxicity studies, exposure assessments, etc.).

Clarify that merely reporting does not establish a lack of compliance with existing product safety standards. (AAFA)

> Agency Response
> The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-010.** Language has been added to indicate that reporting information does not necessarily mean there is a violation of existing safety standards or laws.

2) Definitions

Clarify that the reporting requirements only apply to products intended to be sold in Washington. (AAFA)

> *Agency Response*
> The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-040.** The definition of "children's product" now specifically states that the rule only applies to manufacturers of children's products that are sold or are to be offered for sale to consumers in the state of Washington.

Define the manufacturer intended target age for the product. (PG)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-040.** The definition of "children's product" now clarifies that usage instructions for children alone do not establish that a product is a children's product.

Include a definition of "intentionally added" chemicals (TIA, PCPC)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-040.** The rule now includes a definition of "intentionally added chemical."

Define "distributor," "produce," "producer," and "retailer." (WRA)

Agency Response
Most of these terms are already defined in the law. The rule language was adjusted to better describe the role of a party who is only a retailer. The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-040.**

We support the definitions as written. (WM)

Agency Response
Thank you for your comment.

Clarify the term "credible and peer-reviewed scientific information". (G)

Agency Response
The law establishes the agency's authority to determine what it considers to be credible information. Our practice to date is to not base decisions solely upon either NGO or industry publications. In those cases where equally credible sources disagree (for example, if IARC and IRIS disagree) it is our policy to use the most conservative determination.

Remove the word 'substrate' from the definition of 'product component.' (DOH)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-040.** The definition of "product component" now refers to a uniquely identifiable material rather than a piece or substrate.

3) Exemptions

Exempt all products already regulated by Washington State or Federal regulatory programs. (ACC, VI)

Exempt trace amounts of all naturally occurring chemicals. (FJATA)

Exempt certain components, for example crystal. (FJATA)

Exempt degradation products. (CSPA)

> *Agency Response*
> The law is very specific regarding what products are and are not considered to be children's products. The law does not provide authority to Ecology to expand the list of exempted products through rulemaking.

Exempt the following products from reporting: OTC drugs, prescription drugs, food, medical devices, dietary supplements, packaging. (GMA, PG, CHPA, ACC, VI, PCPC)

> *Agency Response*
> The law already exempts these products from the reporting requirement. Wording in the rule has been clarified in response to this comment; see **WAC 173-334-040.** The requested items have been specifically listed as exemptions from the definition of "children's product."

4) Reporting List

Exclude banned chemicals from the list.. (TTT)

> *Agency Response*
> Most bans apply to specific uses (such as BPA in baby bottles) and do not address all possible or even likely uses of the chemical.Experience has shown that just because a chemical is banned does not mean it is not used.

Neurotoxicity should be used as a criterion for chemicals in future revisions of the list. (WTC, 82 Private Citizens)

> *Agency Response*
> The algorithm used by the agency was based on expert input provided by Dr. Catherine Karr at the University Of Washington School Of Public Health, and the Washington Department of Health. We will revisit inclusion of this endpoint in future revisions.

Chemicals need to be added to the list. (DOH, WTC, King Co. DNR, 82 Private Citizens)

Specifically –

Lead (DOH, WTC, King Co. DNR, 82 Private Citizens)

Agency Response
Because of concerns about possible pre-emption legal challenges due to current federal regulations, the agency has decided to not include lead in this version of the reporting list of chemicals. We will revisit this topic in future revisions.

The six phthalates listed under CSPIA (DOH, WTC, 82 Private Citizens)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-130.** All six phthalates have been added to the list. Concerns about federal pre-emption are not as clear for phthalates as they are for lead. Since all six phthalates meet both the hazard and potential for exposure criteria established in the law, Ecology decided to include these chemicals on the list.

Chemicals need to be removed from the list. (SEHC, AWB, CERC, ACC, VI, WRA, PCPC, JnJ, SIRC, GMA, FJATA, APERC, TIA)

Specifically –

Styrene monomer (SIRC)	Octamethylcyclotetrasiloxane (SEHC)	Cadmium (FJATA)
4-hydroxybenzoic acid (GMA)	Phenols (ACC, TIA, APERC)	Bisphenol A (ACC, GMA)
N-Butanol (ACC, TIA)	Methyl ethyl ketone (ACC, TIA)	Parabens (PCPC, TIA, GMA, JnJ)

All of the following (TIA) –

Antimony & compounds
Butylated hydroxyanisole; BHA
Methyl paraben
Molybdenum & compounds
Propyl paraben
n-Butanol
Styrene monomer
Phenol
Solvent Yellow -14
Nonylphenol
2-ethyl-hexyl-4-methoxycinnamate
4-Nonylphenol; 4-NP
4-tert-Octylphenol
4-octylphenol
perfluorooctanyl sulphonic acid PFOS
Benzophenone-2 (Bp-2)
Butyl paraben
Estragole
Ethyl paraben
Hexabromocyclododecane
Hexachlorobenzene
Hexachlorobutadiene
Octamethylcyclotetrasiloxane
p-Hydroxybenzoic acid
Pentachlorobenzene
Tetrabromobisphenol A
methyl ethyl ketone

Agency Response
The agency believes all of the chemicals on the reporting list meet both the hazard and potential for exposure criteria established in the law. The specific justifications for each chemical on the reporting list can be found on the department's website.

5) Notification Content

We applaud the department's recognition of the need to have a process so that companies can request that certain information be treated as confidential business information (CBI). (AAFA, ACC)

Agency Response
Thank you for your comment. It is important to understand that merely requesting that information be treated as CBI does not mean that the agency will approve the request.

Clarify what types of information can be submitted under 090- (g) ("any other information the manufacturer deems relevant to the appropriate use of the product"). (G)

Agency Response
The law leaves it up to the manufacturer to determine what additional information is relevant for any given report. As this is not a regulatory requirement, Ecology did not adjust the rule language in response to this comment. (This language is now found under **WAC 173-334-080 (g).**)

6) Providing notice

Allow foreign entities to provide reports on behalf of importers or brand owners with a presence in the US, as long as enforcement is not precluded. (WM)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-090.** The rule now includes a hierarchy for determining the party responsible for providing the required notice and does not preclude delegating notice to foreign entities.

Exempt importers from the obligations of a manufacturer if the importer:
(a)obtained written assurances from the producer that the producer would comply with the notification requirements herein,
(b) reasonably relied on those assurances,
(c) promptly notified the State of producer's noncompliance after becoming aware of producer's noncompliance, and
(d) reasonably cooperates with the State, including stopping sale of the product, as applicable. (WRA)

Agency Response
The law specifically includes importers in the definition of “manufacturer” and the notification requirements apply to manufacturers. The law does not allow for the commenters suggestion..

Do not use sales data to prioritize reporting. (TIA)

Agency Response
The agency decided to use gross sales as a proxy for the number of products children will potentially come into contact with. Those companies having the largest gross sales are being asked to report first.

If the reporting schedule is based on sales, it should be gross sales for children’s products only. (TIA, ACC, CSPA)

Agency Response
The definitions and exemptions in the CSPA that define “children’s product” would make it difficult for all parties to determine the gross sales of just children's products. Also, some manufacturers indicate that this type of detailed information should be considered CBI.

Clarify who has to report. Do multiple parties need to report on the same product? Who is the responsible party? (TTT)

Agency Response
Multiple parties do not need to report on the same product. The wording in the rule has been clarified in response to this comment; see **WAC 173-334-090.** The rule language now establishes a hierarchy for the party responsible for providing notice.

The examples for the tiers of products should be consistent with to the ‘class’ descriptions in the GS1 global classification system. (WM)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-110.** The language referencing car seats was removed from the examples of products in Tier 2.

Clarify the scope of products in Tier 1 beyond personal care. (WM)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-110.** The rule language now specifies that only mouthable children’s products intended for children three and under are included in Tier 1 reporting.

Clarify the description of Tier 4 product components . (TIA, G)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-110.** The rule language adopts the standard of "reasonable foreseeable use and abuse" with regard to which components can be expected to come into contact with the child's skin or mouth. This standard is typical of other toy regulations, including US federal law and European Union standards.

Eliminate the Tier 4 category. (ACC, AWB, CERC, WRA)

Agency Response
Experience has shown that on occasion a material which the manufacturer thought would never come into contact with a consumer did end up coming into contact with them. But it should be noted that any reporting for Tier 4 products would require that the rule be amended.

Describe the for trade associations to follow if they aggregate reporting for manufacturers of different sizes. (AAFA)

Agency Response
The trade association would need to follow the reporting schedule established by the rule for the respective manufacturer categories and product tiers. For some trade associations this could mean they enter data into the system on different target dates.

Make the reported information available to the public. (WTC, G, 82 Private Citizens, DOH, WSNA, WashPIRG)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-080.** As stated in the rule any information submitted to the agency which is not CBI will be available to public. Wording has been added to the rule also clarifying that if the agency has the resources we will post the information on the internet even if no one has specifically requested it.

7) Revision of the list

The department should not constrain itself to a limit of no sooner than 2 years for possible revisions. (SEHSC)

We support the current revision schedule. (King Co. DNR, WM, VI)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-070.** The wording in the rule which specified a time-frame for

revisions has been removed. The rule will be updated as the need arises and as resources allow.

Provide further clarification regarding the quality of scientific information used to revise the list. (ACC, GMA, G)

Agency Response
The law establishes the agency's authority to determine what it considers to be credible information. Our practice to date is to not base decisions solely upon either NGO or industry publications. But it important to state that in those cases where credible sources disagree (for example, if IARC and IRIS disagree) it is our policy to use the most protective determination.

Provide an opportunity for public comment when the reporting list is revised. (AAFA, WM)

Agency Response
The department can only add chemicals to, or remove chemicals from, the reporting list by amending this rule in accordance with the requirements of the Administrative Procedure Act, chapter 34.05 RCW, including opportunities for public comment.

Specify the specific amount of time it will take the agency to make decisions on petitions to modify the list. (SEHSC)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-070.** These sections have been consolidated into one section and now specify that the department will review petitions in accordance with the Washington Administrative Procedures Act.

8) Criteria for Evaluation of Chemicals

It is not clear how the agency came-up with the list of reporting chemicals. There is a need to better document why a chemical is on the list. (G, TIA, VI)

We have concerns with the criteria the agency used to come-up with the list of reporting chemicals. It should be a more risk-based approach. (GMA, TIA, FJATA, ACC)

We commend how the department came-up with the list of reporting chemicals. (King Co. DNR, VI)

Do not include a parent chemical on the list if the only justification is that is degrades to a chemical meeting the criteria used for creating the list unless the degradation occurs during ‘reasonable and foreseeable use and abuse’ of the children’s product. (CSPA)

Agency Response
All of the chemicals on the reporting list meet both the hazard and potential for exposure criteria established in the law. Experience has shown that chemicals degrade and that degradation products can cause siginificant health concerns. The specific reasons for this for each chemical on the reporting list can be found on the department's website.

Do not rely on the EU Endocrine Disruptor list to place chemicals on the reporting list. (ACC, TIA, GMA, APERC)

Agency Response
The EU Endocrine Disruptor List as was only used as an initial screening tool in phase II. During phase III a more thorough review each chemical was conducted. The results of this additional review are summarized for each chemical on the reporting list on the department's website.

Do not rely on REPROTEXT to place chemicals on the reporting list. (ACC, TIA)

Agency Response
REPROTEXT is a commercial database from Thomson Reuters that reviews the full range of health effects of industrial chemicals commonly encountered in the workplace. It describes the effects on reproduction and development and gives each chemical a letter rating for reproductive hazard. Ratings are based on information from literature reviews, original studies, and material safety data sheets. Complex mixtures are given the highest ranking of any ingredient for reproductive hazard, regardless of percent composition. General toxicity rankings for mixtures are based on actual test data or, where data are lacking, are estimates based on knowledge of the composition and toxicity of the ingredients. We relied on REPROTEXT as an initial screening tool in phase II. During phase III a more thorough review of each chemical was conducted. The results of this additional review are summarized for each chemical on the reporting list in on the department's website.

Clarify the criteria for 'potential for exposure', including the concept of 'reasonable and foreseeable use and abuse', and the agency's meaning of 'tier 4' product components. (TIA)

Agency Response
The wording in the rule has been adjusted in response to this comment; see **WAC 173-334-110.** The rule language has incorporated the "reasonable and foreseeable use and abuse" standard to define Tier 4 components. If during reasonable and foreseeable use and abuse, there is no contact with the component, it would be reported in Tier 4.

There are mistakes in your phase II score sheet for Phenol and Bisphenol A. (ACC, GMA)

Agency Response
We have double checked the score-sheet and have found no mistakes. The comment regarding phenol may be the result of misinterpreting the information presented on the score-sheets. The commenter is correct that Phenol (CAS# 108-95-2) was not identified by Prop 65 or the National Toxicology Program (NTP) as a developmental/reproductive toxicant; however, this was not used as the basis for listing. The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) was used as the basis for listing.

With regard to Bisphenol A; the commenter is correct in stating "BPA was reviewed in 2010 by the Prop 65 DARTIC (Developmental and Reproductive Toxicant Identification Committee) and they declined to list it." The score-sheet reflects this fact. Prop 65 was not used as a basis for ranking.

Also the commenter stated "WA DoE's approach to ranking NTP's Center for Evaluation of Risk to Human Reproduction (CERHR) findings should follow the actual classification used by the authoritative body, as it did in the case of every other source. To be consistent, CERHR's rankings should be applied directly as are all rankings from all other sources. The logical approach, following rankings for other systems, would be that the determination for the substance would be downgraded to 'Bad.'" The NTP CERHR monograph concluded that there was "some evidence of adverse effects" for reproductive toxicity in laboratory animals. The score-sheet correctly reflects this. In the methodology used, this conclusion results in a ranking of "Severe."

Ecology should use more neutral terms when characterizing toxicity. (ACC)

Agency Response
We agree. We were trying to use terms that made it clear that there was some hazard even for those having the lowest score. In any future revisions we will be sure to use more neutral terms.

9) Concerns about documents used to evaluate economic impacts

The Preliminary Cost-Benefit, Least Burdensome Alternative Assessment and the Small Business Impact statement are not fair or not clear. (AWB, WRA, SR, TTT)

Agency Response
We clarified both documents to better describe the process used to create them. See the department's website.

This should be a federal issue. Washington should not be adding another regulation that will be hard on small business. (TTT)

Agency Response
The legislature passed the Children's Safe Product Act in 2008. This rule establishes mechanisms to carry out that law. Ecology's extensive stakeholder

work and economic analyses have demonstrated the rule as written to be the most effective and least burdensome means to carry out the law. Your comment on the need for comprehensive federal reform is noted.

10) Enforcement

The rule should reflect the differences in due diligence standards for responsible entities without direct knowledge. (WM)

Agency Response
The agency will provide guidance in an attempt to help clarify this and other issues regarding due diligence (see the department's website). However, each situation will need to be evaluated on a case by case basis. **WAC 173-334-120** specifies the standards for manufacturing control programs and due diligence.

11) Level of Reporting

Require the manufacturer to report information in enough detail so that anyone can tell which specific product the report is for. (WTC, WSNA, WashPIRG, PP, 82 Private Citizens)

Require the manufacturer to report information in enough detail so that anyone can tell which specific product and which component of that product the report is for.

Agency Response
Ecology understands the desire of consumers to know what is in the products they buy. However the sheer number of products and chemicals is such that consumers would have to seach hundreds of thousands – even millions of records- to compare the ranges of chemicals present in products. Even then, they would not know which products are least harmful unless they also know where on the potential for exposure from each product. For example, if a sippy cup contains a chemical of concern on the rim of the cup, the potential for exposure is much different than if the chemical was only present on the bottom of the cup. Ecology considered this approach and determined that it was not practical for the consumer, the agency or the notifiying party. Instead, we chose to require information to be reported by product category and product component, significantly reducing the amount of data reported but still providing enough information to allow the agency to determine which product categories and product components are most likely to harm children.

The level of reporting was changed in the rule so that the reporting will be at the brick level for all products. In addition, we increased the number of ranges to provide more information on the level of chemicals present in products..

Require manufacturers to report the number of units sold.

Require manufacturers to report the number of products represented by each in that range . (DOH, WTC)

Agency Response
Requiring manufacturers to provide information on the number of units sold or number of products is not consistent with the approach taken by the agency in this rule.

Reporting by product category and component is a realistic approach. (WM)

Agency Response
Comment noted.

Base the reporting requirement on the weight of the entire product, not the component. (TIA)

Agency Response
The agency considered this approach but concluded that in far too many cases the weight of the entire product would dilute the concentration of the chemical in a component, preventing the collection of meaningful data.

This is the approach used by the European Union's REACH program. However, 6 member states (France, Germany, Belgium, Sweden, Denmark, and Austria), including the three with the largest economies, disagree with this approach (see European Chemicals Agency, "Guidance on Requirements for Substances in Articles," Draft Version 2, December 2010.).

12) Reporting Trigger Values

Increase the reporting Trigger Values. (TIA, AAFA, PCPC, JnJ, AWB, FJATA, GMA, CERC, AFIRM, CSPA, SEHSC, PCPC, ACC, WRA, VI)
Reduce the reporting Trigger Values. (DOH, WSNA, WashPIRG, WTC, WPSR, PP, 82 Private Citizens)

The current trigger of 40ppm is sufficient. (G)

Agency Response
See response 13 below for Intentionally Added Chemicals and Contaminants.

13) Intentionally Added Chemicals and Contaminants

Require reporting only for chemicals which are intentionally added. (TIA, AAFA, PCPC, JnJ, AWB, FJATA, GMA, CERC, AFIRM, CSPA, SEHSC, PCPC, ACC, WRA, VI, SIRC, WM)

Require reporting for all chemicals in a product without regard for how they got there. (DOH, WSNA, WashPIRG, WTC, 82 Private Citizens)

Agency Response

Reporting trigger values and the the issues of intentionally added chemicals v. contaminants are interrelated topics best addressed together. Thougth the positions expressed on these issues were generally mutually exclusive, Ecology considered the merits of each before developing a new approach.

With one exception, all commenters believe the 40 ppm trigger level to be inappropriate. Some commenters believe that any amount at all of a CHCC should be reported while others believe that anything below 1000 ppm should not be required. After considerable research, Ecology concluded that to be implemented, the rule needs to specify a reporting trigger but that it had to be applicable to each chemical and each matrix.

We also concluded that 1000 ppm does not reflect whether or not a chemical is intentionally used or whether the use of the chemical is safe. While this value is used by the European Union's Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) program, the REACH program does not assert that this value is a health- or safety-based value, or that any product with a chemical below this level is safe. This value was selected to try to keep the initial reporting manageable because the REACH reporting requirements apply to an enormous universe of products and chemicals (all chemicals that are intended to be released from all products.) REACH has a much more comprehensive scope of chemicals, products, and potential restrictions than the CSPA. Furthermore, Governor Gregoire's veto message directed Ecology to "rely on safety testing conducted in the European Union and California, to the extent they provide a reasonable assurance of safety, in order to help establish a degree of consistency for the industry." Both of these jurisdictions use many approaches to control the chemical content of products, many of which are more restrictive than the 1000 ppm threshold. In the European Union:

- *Annex 17 of REACH*: Annex 17 of REACH does establish health-based restrictions. These values have been used to ban, limit the allowed concentration, or limit the allowed use of over 80 specific chemicals, as well as "any" substance which has similar characteristics to those we used in creating our list of chemicals. There are very few cases where the value of 1,000ppm is used for a limit. Often where the chemical could be used in a children's product (toys, clothing, personal care products, etc.) it is banned completely, restricted to very few uses, or only allowed at very low concentrations. The restrictions established in Annex 17 for some of the chemicals on the CSPA list are:
    - 75-01-4 Vinyl Chloride – banned from some products – aerosols
    - 71-43-2 Benzene – limited to 5ppm in its free state for toys
    - 7440-43-9 Cadmium – banned for many uses

- *Toy Directive (Directive 2009/48/EC)*: A total of 22 CSPA chemicals are also restricted by the EU Toy Safety Directives that enter into force in July 2013. Several are classified as carcinogenic, mutagenic, or toxic for reproduction (including vinyl chloride, benzene, several phthalates, perfluorooctanyl sulfonates or PFOS, and mercury) and therefore not permitted in "toys, in components of toys or in micro-structurally distinct parts of toys." Migration limit values that correspond to a concentration much less than 1000 ppm are established for several other metals (antimony, arsenic, cadmium, cobalt, and mercury) that are included on the CSPA list.

- *Cosmetics Directives (including Directive 76/768/EEC)*: There are many hundreds of chemicals which are banned from being part of the composition of cosmetic products, including some which are included on the CSPA list (e.g. antimony, benzene, cadmium, mercury, vinyl chloride, and dioxane.) Additionally, there are 64 other chemicals which are only authorized for use in certain concentrations. Including some which are on our reporting list, such as formaldehyde and phenol.

Manufacturers who sell toys or personal care products in Europe must comply (or will have to comply within the next couple of years) with standards limiting the use of many CSPA chemicals to values considerable lower than 1000 ppm.

In California:

- *Proposition 65:* Proposition 65 does not require reporting, but does require product labeling. There are currently more than 700 unique substances and classes of chemicals on the Prop 65 list, which was used as a source for identifying and prioritizing chemicals to be included on the CSPA reporting list. Businesses are responsible for determining whether their products contain a listed chemical at a level above a "safe harbor" limit. Businesses must affix a warning label on any product that contains one or more listed chemicals over safe harbor limits; labels do not necessarily specify which chemicals are present or at what levels. Manufacturers must determine what concentration in their product warrants including a Proposition 65 label on their product, and in many cases the product concentration would likely be well below 1000ppm.

- *Safe Cosmetics Act of 2005:* The California Safe Cosmetics Act requires that for all cosmetic products sold in California, the manufacturer, packer, and/or distributor named on the product label must provide the California Department of Public Health a list of all cosmetic products that contain any ingredients known or suspected to cause cancer, birth defects, or other reproductive harm. This law currently applies to over 700 chemicals. There is no reporting trigger in this law; any amount that is intentionally added must be reported.

Manufacturers who sell products in California already need to know if over 700 chemicals are present in their products.

Ecology determined that intentionally added chemicals (i.e. those that serve a function in the product) offer the best opportunity for substitution with a safer alternative and should be where we focus most of our attention. Finally, we recognized that contaminants (those chemicals that are present but do not serve a function in the product) could be a significant potential source to children and could not be ignored.

The proposed rule (see proposed **WAC 173-334-080**) reflects these changes. We are proposing separate reporting requirements for intentionally added chemicals and for contaminants. The proposed approach closely mirrors the approach used by the US EPA's Design for the Environment (DfE) program. Within the United States, the DfE program is considered a gold standard for government programs designed to address chemicals in products. This program is widely respected amongst both NGOs and business, and has been used to evaluate and certify over 2,500 products. It is primarily targeted to formulated products, including cleaners and detergents, but EPA staff indicate that it can be applied to fabricated products as well. Any amount of an intentionally added chemical (an ingredient in the formulation) must be reported as part of the process of certification under the DfE program. Historically the program has required reporting for any amount of a contaminant above 100ppm, but currently is investigating to see if this requirement should be made more stringent. If deemed feasible, the program may simply not allow contaminants to exceed 100ppm for products to obtain DfE certification.

The proposed rule reflects the following approach:

- For intentionally added chemicals, the lower limit is established by analytical method. We have decided to use the Practical Quantitation Limit (PQL) to establish this lower limit. The PQL is a concept developed by the EPA. It is meant to take into account the real world factors associated with any laboratory and the matrix the chemical is in. A general definition for a PQL is the lowest concentration that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness, and comparability during routine laboratory operating conditions. This value is based on scientifically defensible, standard analytical methods. It is understood that the value for a given chemical could be different depending on the matrix the chemical is in and the analytical method used. Any PQL used by the testing laboratory must be scientifically defensible.

- For contaminants, if the contaminant occurs in the product above 100 ppm it must be reported, unless it can be demonstrated that the company had in place a due diligence system to keep the concentration of contaminants

as low as reasonably possible. The 100 ppm level is consistent with policies established in EPA's Design for the Environment program. The due diligence provision is provided to both encourage companies to minimize the presence of CHCCs in their products and to clarify how the agency will implement this approach. See **WAC 173-334-120**. Ecology will provide draft guidance on this issue as well (see the department's website).

Index of Commenters

Name	Representing	Acronym (if any)	Topics Commented On
Losey, Barbara	Alkylphenols & Ethoxylates Research Council	**APERC**	8
Lamar, Steve	American Apparel and Footware Association	**AAFA**	1, 5, 6, 7, 12, 13
Duvall, Amy	American Chemistry Council	**ACC**	1,3,5,6,7,8,12,13
Mason, Ann	American Chemistry Council Formaldehyde Panel	**ACC**	1,3,5,6,7,8,12,13
Berry, Leslie	American Chemistry Council Ketones Panel	**ACC**	1,3,5,6,7,8,12,13
Berry, Leslie	American Chemistry Council Oxo Process Panel	**ACC**	1,3,5,6,7,8,12,13
Busch, Jon	American Chemistry Council Phenol Panel	**ACC**	1,3,5,6,7,8,12,13
Hentges, Steve	American Chemistry Council Polycarbonate/BPA Global Group	**ACC**	1,3,5,6,7,8,12,13
Utz, Pam	Apparel & Footware International RSL Management Working Group	**AFIRM**	12,13
Nelson, Grant	Association of Washington Business	**AWB**	6,8,9,12,13
Cooney, Glen	Consumer Electronics Retailers Coalition	**CERC**	6,12
Al-Mondhiry, Rend	Consumer Healthcare Products Association	**CHPA**	2,3
Power, Kristin	Consumer Specialty Products Association	**CSPA**	3,4,6,8,
Rothstein, Zachary	Fashion Jewelry and Accessories Trade Association	**FJATA**	3,4,8,9,12,13
Lewandowski, Tom	Gradient	**G**	1,2,5,6,7,12
Jack, Maia	Grocery Manufacturers Association	**GMA**	1,3,4,7,8,12,13
Struyk, William [JJCUS]	Johnson & Johnson	**JnJ**	4,12,13
Galvin, Dave	King Co. Depart. Natural Resources and Parks	**King Co DNR**	4,7,8
Myers, Tom	Personal Care Products Council	**PCPC**	2,3,12,13
Dyer, Anna for Allen, Jennifer	Planned Parenthood	**PP**	4,6,8,11,12,13
Adams, Tamara	Private Citizen		4,6,8,11,12,13
Aegerter, Bob	Private Citizen		4,6,8,11,12,13
Anderson, Brooks	Private Citizen		4,6,8,11,12,13

Angell, Bryony	Private Citizen		4,6,8,11,12,13
Antolin Trudy	Private Citizen		4,6,8,11,12,13
Bangs, Leigh	Private Citizen		4,6,8,11,12,13
Banse Liz	Private Citizen		4,6,8,11,12,13
Benefield, Earlene	Private Citizen		4,6,8,11,12,13
Bergholm, Yvonne	Private Citizen		4,6,8,11,12,13
Biery, Boni	Private Citizen		4,6,8,11,12,13
Brady, Patricia	Private Citizen		4,6,8,11,12,13
Bryant, Bill	Private Citizen		4,6,8,11,12,13
Burrows, Beth	Private Citizen		4,6,8,11,12,13
Callahan, Cindy	Private Citizen		4,6,8,11,12,13
Cappio, Gretchen	Private Citizen		4,6,8,11,12,13
Carlsen, Debbie	Private Citizen		4,6,8,11,12,13
Cates, Edward	Private Citizen		4,6,8,11,12,13
Coates-Robertson, Jamie	Private Citizen		4,6,8,11,12,13
Colangelo, Annapoorne	Private Citizen		4,6,8,11,12,13
Cornelsen, Christy	Private Citizen		4,6,8,11,12,13
Cupiccia, Jami	Private Citizen		4,6,8,11,12,13
Davis, Galen	Private Citizen		4,6,8,11,12,13
Doty, Beverly	Private Citizen		4,6,8,11,12,13
Dyer, Garrison	Private Citizen		4,6,8,11,12,13
Elliott, Ingrid	Private Citizen		4,6,8,11,12,13
Ellis, Scott	Private Citizen		4,6,8,11,12,13
Erwin, Michelle	Private Citizen		4,6,8,11,12,13
Foley, Sarah	Private Citizen		4,6,8,11,12,13
Donahue, G	Private Citizen		4,6,8,11,12,13
Garst, Sam	Private Citizen		4,6,8,11,12,13
Ginsburg, Joe	Private Citizen		4,6,8,11,12,13
Grady, Richard	Private Citizen		Statement of rule importance
Guse, Samantha	Private Citizen		4,6,8,11,12,13
Guth, Dorothy	Private Citizen		4,6,8,11,12,13
Haberly, Brian	Private Citizen		4,6,8,11,12,13
Hamann, Patricia	Private Citizen		4,6,8,11,12,13
Hamer, Suzanne	Private Citizen		4,6,8,11,12,13
Harris, James	Private Citizen		4,6,8,11,12,13
Havens, Lorena	Private Citizen		4,6,8,11,12,13
Hinton, Colleen	Private Citizen		4,6,8,11,12,13
Hirsch, Evan	Private Citizen		4,6,8,11,12,13
Hoggard, Laurie	Private Citizen		4,6,8,11,12,13
Holman, Cherie	Private Citizen		4,6,8,11,12,13
Hostetter, Suzanne	Private Citizen		4,6,8,11,12,13
Jancoski, Loretta	Private Citizen		4,6,8,11,12,13
Jaques, Helga	Private Citizen		4,6,8,11,12,13
Kelly, Angela	Private Citizen		4,6,8,11,12,13
Krell, Mieko	Private Citizen		4,6,8,11,12,13
Kuehl, Lillian	Private Citizen		4,6,8,11,12,13

Laz, Thom	Private Citizen		4,6,8,11,12,13
Logan, Kerry	Private Citizen		4,6,8,11,12,13
Lott, Alan	Private Citizen		4,6,8,11,12,13
Martin, Deborah	Private Citizen		4,6,8,11,12,13
Meyer, Mickie	Private Citizen		4,6,8,11,12,13
Mikalson, Claire	Private Citizen		4,6,8,11,12,13
Mikkelsen, Michelle	Private Citizen		4,6,8,11,12,13
Mitts, Jared	Private Citizen		4,6,8,11,12,13
Moore, Robert	Private Citizen		4,6,8,11,12,13
Morris, Dan	Private Citizen		4,6,8,11,12,13
Mullen, Kay	Private Citizen		4,6,8,11,12,13
Petersen, Deborah	Private Citizen		4,6,8,11,12,13
Peters, Thom	Private Citizen		4,6,8,11,12,13
Price, Karen	Private Citizen		4,6,8,11,12,13
Pringle, Bruce	Private Citizen		4,6,8,11,12,13
Queary, Bart	Private Citizen		4,6,8,11,12,13
Rieger, Reingard	Private Citizen		4,6,8,11,12,13
Rivero, Ana	Private Citizen		4,6,8,11,12,13
Roberts, Cal	Private Citizen		4,6,8,11,12,13
Rolland, Janna	Private Citizen		4,6,8,11,12,13
Rolland, Seth	Private Citizen		4,6,8,11,12,13
Romito, Rick	Private Citizen		4,6,8,11,12,13
Rosewarne, Heather	Private Citizen		4,6,8,11,12,13
Sammons, Valerie	Private Citizen		4,6,8,11,12,13
Slemons, Lia	Private Citizen		4,6,8,11,12,13
Solomon, Laurie	Private Citizen		4,6,8,11,12,13
St. Martin, Darlene	Private Citizen		4,6,8,11,12,13
Thompson, Laurie	Private Citizen		4,6,8,11,12,13
Truskoff, Lou & Joan	Private Citizen		4,6,8,11,12,13
Villines, Monica	Private Citizen		4,6,8,11,12,13
Vos, Johari	Private Citizen		4,6,8,11,12,13
Wahosi, Mare	Private Citizen		4,6,8,11,12,13
Weathers, Corey	Private Citizen		4,6,8,11,12,13
Wilhelm, Joellen	Private Citizen		4,6,8,11,12,13
Zimmerly, Elizabeth	Private Citizen		4,6,8,11,12,13
Guay, Chris	Procter and Gamble Co.	**PG**	2,3
Fleece, Jamie	Silicones Environmental Health and Safety Council	**SEHSC**	7
Lam, Ray	Silk Road	**SR**	9
Snyder, Jack	Styrene Information and Research Center	**SIRC**	4
Rickert, Allen	Top Ten Toys	**TTT**	4,6,9
Hackman, Andy	Toy Industry Association	**TIA**	1,2,4,6,8,11,12,13
Blakey, Allen	Vinyl Institute	**VI**	3,6,7,8
Head, Thomas	Wal Mart	**WM**	1,2,6,7,10,11,12,13
Guichard, Maryanne	Washington Department of Health	**DOH**	2,4,11

Hart, Laura	Washington Physicians for Social Responsibility	**WPSR**	4,6,8,11,12,13
Johnson, Mark	Washington Retail Association	**WRA**	2,6,9
Aragon, Sophia	Washington State Nurses Association	**WSNA**	4,6,8,11,12,13
Schreder, Erika	Washington Toxics Coalition	**WTC**	4,6,8,11,12,13
Brough, Steve	WashPIRG	**WashPIRG**	4,6,8,11,12,13