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with Attachments, and Public Hearing Transcript
for Supplemental Proposed Rule**

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Grice, Joshua (ECY)

From: Tamara Adams [moon_stone@comcast.net]
Sent: Monday, June 13, 2011 6:02 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Tamara Adams
17725 Hall Road Apt. 109
Bothell, WA 98011

Grice, Joshua (ECY)

From: Bryony Angell [bryony_angell@hotmail.com]
Sent: Wednesday, June 15, 2011 8:19 AM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Bryony Angell
1718 NE 124th St
Seattle, WA 98125

Grice, Joshua (ECY)

From: Earlene Benefield [earleneb@comcast.net]
Sent: Tuesday, June 14, 2011 6:39 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Earlene Benefield
11043 108th place NE
Kirkland, WA 98033

Grice, Joshua (ECY)

From: Bates, Stacey [Stacey_Bates@americanchemistry.com]
Sent: Wednesday, June 15, 2011 12:47 PM
To: Williams, John (ECY)
Cc: Berry, Leslie
Subject: Comments: Washington State Department of Ecology's WAC 173-334
Attachments: OPP Comments on WA State CHCC.PDF

Mr. Williams,

The American Chemistry Council Oxo Process 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.

Stacey Bates – Chemical Products and Technology Division

Stacey_bates@americanchemistry.com

American Chemistry Council | 700 – 2nd Street NE | Washington, DC | 20002

O: (202) 249-6728 |

www.americanchemistry.com

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June 10, 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 Oxo Process Panel¹ (Panel) appreciates the opportunity to comment on the Washington State Department of Ecology's (DOE) WAC 173-3342², 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). 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 the objective of several concepts in the proposed regulation; however, we do not support the inclusion of n-butanol on the DOE's CHCC list. As discussed in this letter and the Panel's January 7, 2011 comments³ (previous comments), n-butanol does not meet the criteria for 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. in quantities that would cause adverse health effect. Therefore, the Panel requests DOE remove n-butanol from the proposed CHCC list.

¹ The Oxo Process Panel members are BASF, Celanese, Eastman Chemical Company and the Dow Chemical Company.

² See http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf.

³ ACC Oxo Process Panel's January 7, 2011 comments on Proposed WAC 173-334, also attached to this letter.



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

n-Butanol is not an HPC, and should not be included on the CHCC reporting list. The DOE's CSPA Pilot Phase 2 score sheet and rationale⁴ for n-butanol reveals that the chemical's severe final toxicity determination is 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 is the overriding indicator that n-butanol's toxicity determination should be considered unsound because the assessment relies on inaccurate and outdated information outlined in our previous comments. Moreover, there is no clear process for an interested party to petition REPROTEXT® to have a chemical's assessment updated. Nonetheless, the Panel intends to contact REPROTEXT to correct the flawed n-butanol assessment and rating.

As previously discussed in our January 2011 comments, a conservative analysis of the n-butanol reproductive and developmental toxicity database included in the 2005 OECD SIDS evaluation would lead to a REPROTEXT® hazard rating of "B" not an "A" 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.

2. The DOE's Exposure Rationale for N-Butanol is Unfounded

The DOE's score sheet assessment and rationale⁵ 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's products relies on several studies from the Danish Ministry of Environment (MOE). According to the DOE's 2009 Children's Safe Product Act Report (CSPAR), the DOE reviewed the Danish MOE's studies to determine their relevance to products sold in the U.S. The CSPAR goes on to conclude 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 products⁶." 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 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.

⁴ See <http://www.ecy.wa.gov/programs/swfa/cspa/pdf/CHCCrationale.pdf>, page 4.

⁵ See <http://www.ecy.wa.gov/programs/swfa/cspa/pdf/CHCCrationale.pdf>, page 4.

⁶ See Children's Safe Product Act Report, July 2009 page 32.

3. Danish MOE Exposures Studies Indicate that N-Butanol Had No Adverse Human Health Effects

If the DOE were to use the cited Danish Ministry of the Environment (MOE) studies⁷ in their exposure assessment, the n-butanol is at such a low concentration that the potential exposure is 28,000 to 10,000,000 times lower than the no observed adverse effect level (NOAEL) for the chemical. After review of the Danish MOE studies and the residual concentrations, the Panel completed the following screening risk assessment for n-butanol and calculated the potential oral and inhalation exposures.

The Panel's screening risk assessment used the oral NOAEL of 125 mg/kg/day reported for n-butanol in the USEPA IRIS report⁸. The systemic inhalation exposure was also compared to the oral NOAEL. This screening risk assessment used a Margin of Safety (MOS) approach to conduct a quantitative exposure assessment where the MOS is the ratio of the animal NOAEL divided by the predicted human exposure. An MOS of 100 or greater is typically acceptable as representing no adverse human health effects⁹. The Danish MOE studies reported the following maximum residual concentrations:

- Slimy toy – TI-01 exterior sample contained 3% of VOC mass resulted in an acute breathing zone vapor concentration of 0.103 µg/m³.
- Tent and tunnel – Product A resulted in a vapor concentration of 10 µg/m³ after 3 hours in the test chamber.
- Perfume in toy – Sample D02 had a breathing zone concentration of 0.9 µg/m³.
- Wooden toy – the n-butanol migration was 14 µg/g weight of product.

It should be noted that the Danish MOE studies did not evaluate exposure to n-butanol beyond the maximum residual concentration in their studies because “The substance was detected in extracts from 5 products and even if the substance is harmful and an irritant it is evaluated to be at such low concentrations that it is not selected for further evaluation”¹⁰.

Nonetheless, the Panel calculated the potential systemic inhalation exposure for the Danish MOE studies using the breathing zone vapor concentration of n-butanol, the inhalation rate for a child, the exposure duration, 100% absorption, and the standard body weight of a child.

⁷ See <http://www.ecy.wa.gov/programs/swfa/cspa/pdf/CHCCrationale.pdf>, page 4 and Danish Ministry of the Environment, Consumer Products Reports 46, 60, 67, and 68. Survey of Chemical Substances in Consumer Products . Accessed at http://www.mst.dk/English/Chemicals/Consumer_Products/Surveys-on-chemicals-in-consumer-products.htm, 2004-2006.

⁸ U.S. Environmental Protection Agency, IRIS (Integrated Risk Information System) for n-Butanol. Accessed at <http://www.epa.gov/iris/subst/0140.htm>, 1990.

⁹ See Danish Ministry of the Environment, Consumer Products Reports 60. Page 33. Survey of Chemical Substances in Consumer Products . Accessed at http://www.mst.dk/English/Chemicals/Consumer_Products/Surveys-on-chemicals-in-consumer-products.htm, 2005.

¹⁰ See Consumer Products Report 60, page 24-25. Migration and health assessment of chemical substances in surface treated wooden toys Danish Ministry of the Environment, Environmental Protection Agency. Survey of Chemical Substances in Consumer Products, 2005. http://www.mst.dk/English/Chemicals/Consumer_Products/Surveys-on-chemicals-in-consumer-products.htm



The inhalation exposure calculations and results are shown in Tables 1 to 3. The potential oral exposure for a child mouthing a wooden toy for three hours/day was calculated following the method described by the Danish MOE studies. The oral exposure calculations and results are shown in Table 4.

The exposure calculations were validated by comparing the results to those performed by the Danish MOE for a second substance. For this validation, exposure for 2-butanone was calculated in Table 2 and exposure for 2-butoxyethanol was calculated in Tables 3 and 4; the calculated exposures matched the values reported by the Danish MOE.

Table 1. Inhalation exposure calculations for perfume in toys.

Parameter	Value	Units	Basis
Substance	n-Butanol		
Measured air concentration for fragrant rubber figures	0.9	$\mu\text{g}/\text{cm}^3$	Danish report page 63, sample D02 for Butanol
Respiration rate	1.9	m^3/hr	Danish default active child
Inhalation absorption	100%	%	Danish assumed 100%
Exposure duration	24	hr	Assumed worst case
Child body weight	10	kg	Danish default page 36
Inhalation exposure	0.2	$\mu\text{g}/\text{kg bw}/\text{day}$	Calculated
Oral NOAEL	125	$\text{mg}/\text{kg bw}/\text{day}$	Butanol from EPA IRIS (1990)
Margin of Safety (MOS)	138,889	unitless	Calculated



Table 2. Inhalation exposure calculations for a slimy toy.

Parameter	Value	Value	Units	Basis
Substance	Butanol	2-Butanone		
	Calculated in this study	Calculated in Danish report		
Sample TI-01 exterior content	3	2.3	%	Danish report Table 3.2 reported 0.2, 2.6, 1, 3 %m/m for Butanol
Breathing zone concentration	0.103	0.079	$\mu\text{g}/\text{cm}^3$	Butanol read across from Danish report Table 6.1
Short term respiration rate	1.2	1.2	m^3/time	Danish default page 65
Inhalation absorption	100%	53%	%	Danish report page 73; assumed 100% for Butanol
Child body weight	10	10	kg	Danish default page 68
Short term inhalation exposure	0.0124	0.0050	$\mu\text{g}/\text{kg bw}/\text{day}$	Calculated
Oral NOAEL	125	594	$\text{mg}/\text{kg bw}/\text{day}$	Butanol from EPA IRIS (1990); 2-butoxyethanol from Danish report
Margin of Safety (MOS)	10,109,001	118,223,071	unitless	Calculated
		matches report for TI-01 exterior		

Table 3. Inhalation exposure calculations for tents and tunnels.

Parameter	Value	Value	Units	Basis
Substance	Butanol	2-Butoxyethanol		
	Calculated in this study	Calculated in Danish report		
Measured air concentration after 3 hours	10	153	$\mu\text{g}/\text{cm}^3$	Danish report Sample A for Butanol; Sample D for 2-Butoxyethanol
Respiration rate	1.9	1.9	m^3/hr	Danish default page 36
Inhalation absorption	100%	100%	%	Danish assumed 100%
Exposure duration	3	3	hr	Danish default page 36
Child body weight	10	10	kg	Danish default page 36
Inhalation exposure	2	29	$\mu\text{g}/\text{kg bw}/\text{day}$	Calculated
Convert units	0.002	0.03	$\text{mg}/\text{kg bw}/\text{day}$	Calculated
Oral NOAEL	125	no data	$\text{mg}/\text{kg bw}/\text{day}$	Butanol from EPA IRIS (1990)
Margin of Safety (MOS)	65,789		unitless	Calculated
Oral LOAEL	no data	69	$\text{mg}/\text{kg bw}/\text{day}$	Danish report page 37
Margin of Safety (MOS)		2,374	unitless	Calculated
		matches report		



Table 4. Oral exposure calculations for a wooden toy.

Parameter	Value	Value	Units	Basis
Substance	2-Butanol	2-Butoxyethanol		
	Calculated in this study	Calculated in Danish report		
Danish measured amount migrated substance per unit weight of product	14	322	µg/g	Table 4 reported 14, 13, 3.3, 2.0, 1.3 for 1-Butanol; used maximum value
Migration from toy	2.94	67.62	µg/cm ²	Report page 36; calculated using 0.3 cm depth and density of 0.7
Time for contact per event	2	2	hr	Danish experiment default
Area of toy	10	10	cm ²	Danish experiment default
Total migration	14.7	338.1	µg/cm ² /hr	Calculated
Oral absorption	100%	100%	%	Danish default assumed 100%
Contact time by child	3	3	hr/day	Danish default
Child body weight	10	10	kg	Danish default
Oral uptake of the substance	4.4	101.4	µg/kg bw/day	Calculated
Oral NOAEL	125	7.6	mg/kg bw/day	Butanol from EPA IRIS (1990); 2-butoxyethanol from Danish report
Margin of Safety (MOS)	28,345	75	unitless	Calculated
		matches report		

3.2 Oral and Inhalation Exposures

As discussed in the above tables, all MOS values were greater than 100 for n-butanol in the Danish MOE studies, therefore, the exposure and MOS were acceptable. The exposure results are summarized as follows:

- Wooden toy – oral MOS of 28,345
- Slimy toy – inhalation MOS of 10,109,000
- Tents and tunnels - inhalation MOS of 65,789
- Perfume in toy - inhalation MOS of 138,889

This screening risk assessment for n-butanol used conservative assumptions and residual concentration values from toys as reported by the Danish MOE studies. The estimated exposures are acceptable as the MOS ranged from 28,345 to 10,109,000 indicating that n-butanol had no adverse human health effects in the Danish MOE studies. Based on the Panel's screen risk assessment of the cited Danish studies we urge the DOE to reconsider the exposure classification for n-butanol.



ACC OPP Comments on DOE CHCC List

June 10, 2011

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4. 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 in quantities that would cause adverse health effect, therefore, n-butanol should be removed from the CHCC reporting 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

Attachment





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 Oxo Process Panel¹ ("Panel") appreciates the opportunity to comment on the Washington State Department of Ecology's ("DOE") WAC 173-334², 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-butanol⁵ 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/m³) throughout gestation and male rats exposed to 6,000 ppm (18,000 mg/m³) 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/m³) 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.

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 CSPA 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 Children⁶

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	

^aMixture 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. Review of N-Butanol REPROTEXT[®]'s TERATOGENICITY Section

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 convert 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 and 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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OPP DOE comments n-butanol

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Grice, Joshua (ECY)

From: Mattias.Bodin@hm.com
Sent: Wednesday, June 15, 2011 11:53 PM
To: Williams, John (ECY)
Cc: Pam_Utz@gap.com
Subject: WA CSPA - Reporting Rule Comments - June 15, 2011 (Gap, Levi, Nike, VF)
Attachments: WA CSPA Reporting Rule 6-15-11 Final.pdf

Dear John,

H&M would like to join the letter submitted by below companies regarding the Reporting Rule under Washington's CSPA.

Any questions, please let me know.

Cordially,

MATTIAS BODIN

GROUP MANAGER, GLOBAL QUALITY DEPARTMENT
H&M HENNES & MAURITZ GBC AB
MÄSTER SAMUELSGATAN 46A
106 38 STOCKHOLM
SWEDEN
PHONE: +46 8 796 5955



Please consider your environmental responsibility before printing this e-mail.

From: Pam Utz
Sent: Wednesday, June 15, 2011 10:44 PM
To: 'jowi461@ecy.wa.gov'
Cc: 'ckra461@ecy.wa.gov'; 'Sean_Cady@vfc.com'; 'Frazier, John'; 'Pidgeon, Elena'; 'Man, Kitty'; 'Goldman, Laurie'; Nathaniel Sponsler
Subject: RE: WA CSPA - Reporting Rule Comments - June 15, 2011 (Gap, Levi, Nike, VF)

Dear John,

Thank you for the opportunity to comment once again on the Reporting Rule under Washington's CSPA. We appreciate your consideration of industry input on how to achieve the State's objectives. Attached is the joint response of Gap Inc., Levi Strauss & Co, Nike Inc, and VF Services, Inc.

Please let us know if you have any questions.

Cordially,

Pam Utz, Director, Product Regulations, Gap Inc.
Nathaniel Sponsler, Manager, Product Regulations, Gap Inc.

Elena Pidgeon, Senior Manager, Product Safety LS Americas, Levi Strauss & Co.
Kitty Man, Ph.D., Global Leader, Restricted Substances, Levi Strauss & Co.

John Frazier, Director of Sustainable Chemistry and Water, Sustainable Business and Innovation, Nike Inc.

Sean Cady, Vice President, Product Stewardship and Sustainability, VF Services, Inc.

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June 15, 2011

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: Reporting Rule

Dear John,

Thank you for the opportunity to comment on the May 4, 2011, revision of the CSPA Reporting Rule (Chapter 173-334 WAC). We appreciate your willingness to engage with us as stakeholders in many contacts over the past year, resulting in three comments to date (Oct.1, Dec. 22, 2010, Feb. 15, 2011). The new elements in the latest version of the Rule prompt an additional comment.

In summary, we have long-established policies and practices in place at our respective companies that ensure the safety of all our products. Our practices are based on a combination of compliance with global legal requirements, established industry product safety standards, our internal risk assessment, and verification systems such as factory audits and product testing. We have found this combination of efforts successful in ensuring that only safe products are produced and sold by our companies. On the other hand, as discussed below, the product testing requirements implicit in the CSPA Reporting Rule do not enhance the safety of children's products. Moreover, requiring companies to expend significant resources simply to determine if any amount of a substance, no matter how minute, is present in the product takes away from the working programs already in place at our companies.

1. CSPA is a reporting law.

The stated goal of CSPA and the Draft Reporting Rule is information gathering. Most Washington retailer-importers, who are responsible for reporting when the manufacturer resides outside the state, must rely on information from their suppliers to fulfill this obligation. They will do this primarily through Material Safety Data sheets (MSDS) prepared by chemical manufacturers which in large part do NOT provide data to the levels required for CSPA. The result is that although CSPA does not mandate testing of children's products to determine concentrations of listed Chemicals of High Concern, as currently written the law would impose a substantial new cost burden on retailers and importers in the State. We do not believe that this has been weighed by legislators nor figured into administrative reviews. This additional testing cost to supply chains both inside and outside of Washington State diverts resources from due diligence activities that companies with a managed Restricted Substances List perform as part and parcel of their manufacturing control programs.

We also believe that the new draft regulation moves beyond the stated goal when it institutes the "PQL"--Practical Quantification Limit¹ in analytical testing--as the trigger for reporting. To support this,

¹ " 'PQL Practical quantification limit' (PQL) means 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. The value for a given chemical could be different depending on the matrix and the analytical method used." (Definitions WAC 173-334-040)

retailer-importers would need to rely heavily on sophisticated laboratory testing to detect 66 and more substances across all children's products. Although we share the goal of strong product stewardship, we do not believe the current approach offered by the rule results in safer product.

In addition to being costly, many of the listed Chemicals of High Concern in the Reporting Rule have no validated test methods for the materials and components used in our industry. Laboratories as well as standard-making bodies do not agree on methods or they modify them individually, which means there will be different PQLs for the same substance. In fact the definition of PQL (footnote 1) makes clear that this trigger level for reporting need not be the same for two importers bringing in an identical product but using different laboratories with different methods and equipment variables. The ensuing difficulties both for compliance and enforcement can be avoided if the trigger for reporting followed the broadly accepted standard for "no effect" used on Material Data Safety Sheets and in regulations like the European REACH (1000 ppm). In any case, companies who invest in testing programs follow test methods with PQLs appropriate to materials in their industry. We suggest that Washington consider the use of established test methods and associated detection levels already applicable to the specified product.

2. "Intentionally added"² substances perform a function in the finished product.

We support in principle the new approach of distinguishing between intentionally-added chemicals and contaminants as established in section 173-334-080 (1). By focusing on those substances purposely added to perform a specific function in finished products, we believe Ecology will collect more meaningful data and help focus agency attention and resources.

However, the new concept of the intentionally-added chemical adds a level of complexity and judgment to reporting. Almost all apparel and footwear products consist of formulations of multiple chemical substances. In textile products, many of these formulations assist early in the manufacturing process, for example, to make a fabric able to accept dye. Although intentionally used, such chemicals are not intended to remain on the fabric or garment as each passes through subsequent processes later in manufacturing. Nor are these substances intended to impart a function or effect in the finished product. By comparison other chemical formulations are intended to persist in the component and perform functions in the product, such as wrinkle-resistance finishes on fabric.

Properly classifying which substances are intended to perform a function in the finished product as opposed to assisting earlier in the manufacturing process requires expert knowledge, and grey areas exist where professional interpretations may conflict. We ask that Ecology carefully consider this reality and defer to manufacturer expertise in differentiating between the two types of substances where there is uncertainty. We believe that only those substances required to be present in the final consumer product to impart a desired function should be covered by the "intentionally added" definition.

In this context it is also important to point out that the Reporting Rule, in trying to define "product component"³, departs from the prevailing standard in other laws: A component is that which can be

² "'Intentionally added chemical' means a chemical in a product that serves an intended function in the product component." (Definitions WAC 173-334-040)

³ "'Product component' means a uniquely identifiable material or coating (including ink or dye) that is intended to be included as a part of a finished children's product." (Definitions WAC 173-334-040)

physically separated from another. Thus a reactive dye, for example, once applied and reacted on the fabric, is not a component because it can no longer be separated from the fabric and analyzed on its own. A coating in contrast can be removed and analyzed. We suggest that Ecology maintain the more standard definition of a product component.

3. Restricted Substances List (RSL) Testing Program is a Manufacturing Control Program

We support the rule changes that acknowledge our and others' commitment to product safety by virtue of effective chemical control policies and practices. The new subsection WAC 173-334-080 (1)(c) states that a "manufacturer need not file a notice with respect to any CHCC that occurs in a product component only as a contaminant if the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component."

We believe this approach promotes responsible chemical management by largely exempting those manufacturers from notification who invest significant resources into Restricted Substances List (RSL) testing programs. We are confident that our respective programs work to effectively minimize the presence of many of the listed substances where they can occur as unintended contaminants of the manufacturing process. We further believe this provision will encourage other footwear and apparel companies to develop robust RSL programs of their own, a key objective of the AFIRM⁴ Group, which we are all members of.

Thank you 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, Manager, Product Regulations, Gap Inc.

Gap Inc.

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.



⁴ www.afirm-group.com

Sean Cady, Vice President, Product Stewardship and Sustainability, VF Services, Inc.



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 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.

About VF

VF Corporation is a global leader in branded lifestyle apparel with more than 30 brands, including *Wrangler(R)*, *The North Face(R)*, *Lee(R)*, *Vans(R)*, *Nautica(R)*, *7 For All Mankind(R)*, *Eagle Creek(R)*, *Eastpak(R)*, *Ella Moss(R)*, *JanSport(R)*, *lucy(R)*, *John Varvatos(R)*, *Kipling(R)*, *Majestic(R)*, *Napapijri(R)*, *Red Kap(R)*, *Reef(R)*, *Riders(R)* and *Splendid(R)*. VF Corporation's press releases, annual report and other information can be accessed through the Company's home page, www.vfc.com.

Grice, Joshua (ECY)

From: Patricia Brady [pattbrady@comcast.net]
Sent: Tuesday, June 14, 2011 4:43 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Patricia Brady
9547 Berkshire Ct SE
Lacey, WA 98513-4844

Grice, Joshua (ECY)

From: Gregory Yahr [gyahr@apparelandfootwear.org]
Sent: Wednesday, June 15, 2011 2:05 PM
To: Williams, John (ECY)
Cc: Steve Lamar; Nate Herman
Subject: AAFA Reporting Rule Comments
Attachments: AAFA - Washington State CSPA Reporting Rule Comments - June 15 2011.pdf

John,

Thank you again for speaking to our Environmental Committee last month. Please find attached AAFA's comments on the Children Safe Product Act Reporting Rule. We'd like to thank you in advance for your consideration as well as the numerous opportunities to comment on this rule. Please feel free to reach out to Steve or myself with any questions.

Regards,

Greg Yahr
Government Relations Representative
American Apparel & Footwear Association (AAFA)
1601 N. Kent Street, 12th Floor
Arlington, VA 22209
Phone: (703) 797-9049
Email: gyahr@apparelandfootwear.org



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June, 15 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 revised Children's Safe Products Reporting Rule (173-334 WAC).

Our comments supplement those submitted earlier in which we offered initial thoughts on an earlier version of the proposed rule, discussed AAFA's environmental educational programming and its support of predictable and harmonized product safety and chemical management programs, and noted the reach AAFA's membership in Washington State, the United States, and the world. A copy of those earlier comments can be found at:

<https://www.apparelandfootwear.org/UserFiles/File/Testimony-Comments/2011/washingtonstatecpsareportingrulecomments110107.pdf>

Of particular importance we do wish to stress our work in educating the apparel and footwear industry supply chain on product safety compliance initiatives, which has been a top priority for AAFA for decades. Over the past three years, AAFA and various international partners have conducted over a hundred webinars, briefings, conferences and training programs, throughout the United States and on four continents on restricted substances, chemical management, and other product safety topics. Two months ago we held our sixth conference on this important topic in China to educate our members' suppliers – our 8th such program in Asia in the past three years. In a few months we will return to Asia to conduct our 1st such conference in Bangladesh.

It is with this in mind that we wish to commend you and your agency for your extensive outreach to interested stakeholders and for conducting a rule making that provided many opportunities to interact with you and examine the regulations as they have evolved. This is an important step in rulemaking that we wish was more prevalent throughout the rest of the country. In addition, we thank you again for presenting an update on the rule to our

Environmental Committee during its May 2011 and May 2012 meetings. Your approach and this regulatory philosophy should be a model for other state and federal agencies.

We would stress, however, that education is an on-going need when it comes to changes in regulations that affect extensive supply chains, such as those that are prevalent in our industry. We will hope to be able to work with your office in the coming months, even after the final rule is promulgated, to help us educate members on the new requirements they will need to follow. Moreover, we would hope that the Department will understand that, with so many conflicting chemical management and product safety initiatives being undertaken on a daily basis, that companies will need time to fully educate their supply chains on these new requirements.

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

Recap

As we understand it, the revised 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 State¹. 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 table⁴ is that most clothing and footwear will fall under Tier 2. Clothing and footwear intended for children age 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).

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

¹ See Chapter 173-334-040 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 2.

² See Chapter 173-334-040 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 2.

³ See Chapter 173-334-040 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 2.

⁴ See Chapter 173-334-110 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 8.

⁵ See Chapter 173-334-090 WAC Children's Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 6.

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 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 revised 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 –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 material or coating (including ink or dye) that is intended to be included as a part of a finished children’s product.”⁹ Notwithstanding further concerns we articulate about the definition of the term “product” below, implicit in that definition is the concept that it is up to the manufacturer to make the assessment over what is uniquely identifiable. Among other things this approach avoids, to a large degree, a one size fits all approach 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 we would urge that this principle be closely followed.

Ensuring manufacturer reporting flexibility is particularly vital since the CSPA is first and foremost a reporting law. Our member companies have established policies and procedures to ensure that they produce and sell safe products. To the extent that the CSPA imposes testing or compliance burdens in addition to or in conflict with those established programs, we will see our members’ efforts to advance product safety undermined. For example, a commonly accepted internal reporting tool - the material safety data sheet (MSDS) - does not provide the kind of precision the CSPA may require. This would force further testing and internal reporting in areas where chemical management and product safety initiatives already suffice. With this in mind we encourage you to continue looking for ways to ensure the CSPA reporting requirement maximizes existing industry protocols and procedures.

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.”

⁶ See Chapter 173-334-140 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf) . pp. 10 -11.

⁷ See Chapter 173-334-060 - 070 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.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_supp.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_supp.pdf). p. 3.

As we mentioned in our previous comments, the draft regulation has two age related requirements (3 and under; 11 and under). However, it is essential to understand that our industry does not communicate on the basis of age. Our industry most often produces products based on size not on age. Therefore pegging regulations to age rather than size could result in varying interpretations of what constitutes a product for a 3 or 11 year old. It is our expectation that the Department will defer to manufacturers to best identify the sizes that correspond to the specific age ranges the Department has articulated.

We thank you for including the concept of “inaccessibility” into the rule.¹⁰ However, we urge you to consider incorporating a formal definition. The concept of inaccessibility is a mainstay of product safety regulations and is well known throughout our industry. A thorough definition of “inaccessibility” will remove uncertainty and potentially burdensome testing requirements. Without a proper definition for “inaccessibility,” companies may be forced to test for chemicals that are inaccessible to humans and therefore pose no threat of harm. Testing components that are inaccessible represents an increased cost with no corresponding increase in safety offered to the consumer.

In principle we support the inclusion of a definition for mouthable but are concerned how the current definition can be read to apply to our industry.¹¹ For example, no component in clothes and shoes appears to meet the 5 cm definition so that would render all clothing and footwear mouthable even though many components of such articles can't even be licked, let alone sucked or chewed on, while the article is being worn. We would recommend addition of a clarifying sentence that reads "In the case of apparel or footwear, a component is considered mouthable only if it is likely to be chewed or sucked on while being worn.

We also have concerns over the draft rules definition of a “product component.”¹² In other product safety regulations, the defining characteristic of a component is its ability to be physically separated from the rest of the garment. The rule as currently written would then consider a reactive dye to be a separate component despite the fact that it cannot be physically separated from the rest of the product. It is important that definitions for common items like this do not vary from regulation to regulation, and instead promote consistency and predictability in the regulatory landscape.

There is also not a definition listed for “safer alternatives assessment.”¹³ Our members may be interested in doing an assessment, but need to know more about what the Department will require. Further to that point, the language in the current draft does not clarify how much of a reduction is needed to qualify as “significant reduction in CHCC.” Both of these are important factors that could potentially impact a company’s ability to conduct a safer alternatives assessment.

We were pleased that the updated rule distinguished between an intentionally added component and a contaminant. Further, section “c” which begins “A manufacturer need not

¹⁰ See Chapter 173-334-110 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 8

¹¹ See Chapter 173-334-040 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 2-3

¹² See Chapter 173-334-040 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 3

¹³ See Chapter 173-334-110 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 8

file a notice with respect to any CHCC...”¹⁴ could be very helpful to companies. However, in order for this clause to have the intended effect, there needs to be more language in the draft to clarify what is needed to qualify for this exemption. At minimum there should be a definition of a “manufacturing control program and due diligence,” but ideally there should also be a prescribed process by which a company can seek this exemption, including reliance on RSLs as discussed below. Further the exemption is complicated because it requires that the manufacturing control program minimize the presence of the contaminant in the component. This caveat will be difficult for most companies to navigate and could negate the usefulness of the clause because most product safety programs are intended to reduce chemical content to meet product safety restrictions, not necessarily to continue minimizing the chemical content in a specific component. We urge you to remove this phrase in the final rule.

We welcome that the Department envisions a regular review regarding changes to the CHCC list. We are pleased with the inclusion of the specific procedure by which the list of CHCC’s will be updated.¹⁵ This will help to ensure a well thought out and thorough dialogue between stakeholders before the list of CHCC’s is changed.

We are particularly pleased that the rule permits manufacturers to report through trade associations. This makes sense from several perspectives, including the additional of an additional filter for confidential business information (CBI) and the opportunity to consolidate 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.¹⁶ 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. However, we are still uncertain as to 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? Based on the update you provided to our committee, our understanding 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 in the rule language and also suggest that all timelines for initial phase-ins be pegged at 12 month intervals.

We strongly agree with the statement in the initial draft regulation that reporting the presence of a CHCC does not indicate a health or safety concern. We are pleased that in this latest draft you have further clarified that reporting the presence of a CHCC does not necessarily mean that there is any violation of existing safety standards or laws.¹⁷

¹⁴ See Chapter 173-334-080 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 4

¹⁵ See Chapter 173-334-070 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 4

¹⁶ See Chapter 173-334-080 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 5

¹⁷ See Chapter 173-334-010 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 1

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.¹⁸ The latest draft regulation indicates that it is the intention of the Department to post all information not deemed Business Confidential Information (CBI) to its web site.¹⁹ We recommend that the Department refrain from doing so. Instead use the information reported for your 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.

Another concern, that we have previously brought to your attention 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 that you continue to work toward ways to reduce this kind of reporting requirement. 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. Currently, for the purposes of this rule a children’s product “only include(s) products that are sold, or are to be offered for sale to consumers in the state of Washington”²⁰ However, based on the wide reach of the internet, it is possible to conclude that any product offered online anywhere could be considered offered for sale in Washington. While, the vast majority of our members sell their products nationwide, several members sell to local markets that do not include Washington. Whether through brick and mortar or online, these companies should not be held responsible to incur a reporting obligation if a consumer buys a product and then transports it to Washington State without their knowledge.

We are concerned that the definition of “practical quantification limit (PQL)” does not seem to take into account testing costs and sample size in addition to the other specified limits. This will help to ensure that business interests’ are represented in the process of creating the PQL’s. Also, we would suggest that generally speaking the PQL should be the lowest typical detection level when testing for that chemical in the product type. To further simplify the reporting requirement, we have a number of recommendations for 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 concerns. 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

¹⁸ 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.

¹⁹ See Chapter 173-334-080 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 5

²⁰ See Chapter 173-334-040 WAC Children’s Safe Products – Report Rule (Draft Regulation http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf). p. 2

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. We further believe this reporting is consistent with the manufacturing control program described in subsection WAC 173-334-080(1)(c).

Another approach some members have taken is obtaining third party certificates which attest to the chemical content of their products. We would encourage the Department to consider these certificates acceptable for reporting purposes as well and outline that acceptance in the final rule. Allowing these certificates to be used will remove an extra burden from the manufacturer, while still providing the information needed by the Department.

Second, we recommend the Department to 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). 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 given stakeholders a more digestible dataset of information than the current list of five reporting categories (of which the 1000ppm is the middle level).

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

Grice, Joshua (ECY)

From: Jamie Coates-Robertson [jamiemountain@yahoo.com]
Sent: Monday, June 13, 2011 5:02 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Jamie Coates-Robertson
8321 172nd Ave NE
Redmond, WA 98052

Grice, Joshua (ECY)

From: Christy Cornelsen [opal_1978@yahoo.com]
Sent: Monday, June 13, 2011 8:10 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Christy Cornelsen
212 E. Hillside Dr.
Warden, WA 98857

Grice, Joshua (ECY)

From: Jami CUPICCIA [pats_98335@yahoo.com]
Sent: Monday, June 13, 2011 11:05 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Jami CUPICCIA
4005 58Th Street Ct Nw
58 TH ST CT NW
Gig Harbor, WA 98335

Grice, Joshua (ECY)

From: Galen Davis [neorenfield@yahoo.com]
Sent: Monday, June 13, 2011 4:00 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Galen Davis
9114 8th Ave NE
Seattle, WA 98115

Grice, Joshua (ECY)

From: wpsr.cherie@gmail.com on behalf of Cherie Eichholz [cherie@wpsr.org]
Sent: Wednesday, June 15, 2011 3:18 PM
To: Williams, John (ECY)
Subject: Comments re CSPA
Attachments: Letter to Ecology 20110615.pdf

Please see attached.

--

Cherie Eichholz, Executive Director
Washington Physicians for Social Responsibility
www.wpsr.org ~ [206.547.2630](tel:206.547.2630)

SAVE THE DATE: Thursday, July 14th, 2011 ~ WPSR's 2011 Annual Dinner

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cherie@wpsr.org

Jessie Duvall, MS-4
jessie@wpsr.org

Idil Levitas
idill@wpsr.org

Kathy Pryor
kathy@wpsr.org

Nick Thorp
nick@wpsr.org

June 15, 2011

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

Dear Mr. Williams:

On behalf of health professionals across Washington State, I am writing today with respect to the Children’s Safe Products Act (CSPA), which was passed in 2008 in response to the significant problem posed by harmful chemicals in common children’s products. I and the entirety of Washington Physicians for Social Responsibility sincerely appreciate the efforts of the Washington State Department of Ecology over these past 3 years, specifically your thoughtful and careful implementation of this law.

As you well know, Washington State enjoys a long history of working to protect the most vulnerable among us and we are sincerely grateful for your past leadership in safeguarding Washington’s children. As physicians and health professionals, advocating for policies in our state that aim to “first, do no harm,” your leadership helps us better do our job ensuring children are able to reach and maintain their full potential, something we believe every human being is entitled to.

As you also know, children are significantly more susceptible to chemical exposures versus adults. Relative to their body weight, they eat more, breathe more, and drink more than adults and thus receive a greater exposure of environmental chemicals and their body burden is increased. In addition, various factors, ranging from behavioral to physiological, make children exceptionally vulnerable to the effects of toxic exposures. To illustrate, children’s innate hand-to-mouth and play behaviors increase their direct exposure to toxicants in the environment; depending on the timing of this interaction, and the stage of their development, they can be particularly susceptible to the damaging effects of chemical exposures. Ultimately, a greater proportion of toxins enter children’s bodies and stay there longer, allowing them more time to exert their damaging effects. These chemicals put children at risk for cancer, developmental diseases, and other health issues.

With this correspondence, I would like to take a moment to urge Ecology’s continued strenuous implementation of the CSPA and ask you to do strengthen the rule under consideration by:

1. Requiring all makers of children’s products intended for children 3 and under to report information immediately.

1604 NE 50th Street, Seattle WA 98105 ~ Phone: 206.547.2630 ~ www.wpsr.org
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2. Requiring companies to disclose how widely a chemical is used in a product category.
3. Doing away with loopholes that let companies off the hook for reporting if a chemical is in a product as a contaminant.

Our goal as health professionals is to help our patients reach their full potential. We cannot do this in isolation. We now have an opportunity to create a robust policy that protects children in a more meaningful way and in doing so, indicating Washington State's clear intention to protect human health, especially that of children, from toxic chemicals with potentially hazardous effects.

Gratefully yours,

A handwritten signature in black ink, appearing to read "Cherie L. Eichholz". The signature is fluid and cursive, with a prominent loop at the end.

Cherie L. Eichholz, Executive Director

Grice, Joshua (ECY)

From: EVA ELLIOTT [ev88ev@yahoo.com]
Sent: Monday, June 13, 2011 8:32 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
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- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

EVA ELLIOTT
2130 N. 63rd St
Seattle, WA 98103

Grice, Joshua (ECY)

From: Ingrid Elliott [elliottshapiro@mac.com]
Sent: Monday, June 13, 2011 4:14 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Ingrid Elliott

Ingrid Elliott
617 W. Howe St.
Seattle, WA 98119

Grice, Joshua (ECY)

From: Matthew Gerhart [mgerhart@earthjustice.org]
Sent: Wednesday, June 15, 2011 12:22 PM
To: Williams, John (ECY)
Subject: Children's Safe Products Act reporting rule
Attachments: Comments on the Children's Safe Products Act Reporting Rule.pdf

Attached please find the comments of the Washington Toxics Coalition on the Children's Safe Products Act reporting rule. Thank you.

Matthew Gerhart

Associate Attorney
Earthjustice
705 Second Ave., Suite 203
Seattle, WA 98104
(206) 343-7340 ext. 1024
www.earthjustice.org<<http://www.earthjustice.org/>>



June 15, 2011

by e-mail to: john.williams@ecy.wa.gov

John R. Williams, Jr.
Department of Ecology
P.O. Box 47600
Olympia, WA 98540-7600

Re: Comments on the Children's Safe Products Act Reporting Rule

On behalf of the Washington Toxics Coalition, Earthjustice submits these comments on the proposed reporting rule implementing the Children's Safe Products Act ("CSPA" or "Act"). We support the requirement in the Children's Safe Products Act that manufacturers disclose the concentration of certain chemicals in children's products. For both policymakers and the public at large, it is vital to know whether children's products contain chemicals that have the potential to harm children. The health of our children should not depend on a guessing game as to the contents of children's products.

Fortunately, the Washington Legislature agreed, and passed a groundbreaking law designed to improve the safety of children's products. The Children's Safe Products Act directed the Department of Ecology, in consultation with the Department of Health, to develop a list of chemicals of high concern to children ("CHCCs"). To produce this list, the agencies collaborated with researchers at the University of Washington to identify the chemicals most capable of causing harm to children, based on potential exposure and effects. The researchers reviewed the available scientific literature and the efforts of other states, the federal government, and other countries. Ultimately, the proposed list of chemicals of high concern to children includes 59 chemicals, such as arsenic, formaldehyde, BPA, and phthalates.

The heart of the CSPA's reporting provision is the requirement that manufacturers of children's products submit an annual report stating the amount of each CHCC in each children's product they produce. Ecology has committed to making these reports available to the public.

The statute requires the annual report to contain the amount of each chemical of high concern to children used in each product -- in either "the product or product component." RCW 70.240.040(4). The requirement to report the concentration of a CHCC in each product serves two broad purposes. On the one hand, it ensures that policymakers have accurate data on the exposure of children to potentially harmful chemicals. On the other hand, the reports would enable consumers to make informed purchases of children's products.

Despite the plain language and purposes of the statute, Ecology has crafted the reporting rule to prevent the public from identifying the amount of chemicals in particular products. Ecology has designed the reporting rule such that a company will report the amount of a CHCC in the product component within each product category. The following table uses hypothetical

examples¹ to illustrate how Ecology's proposed rule will deprive both policymakers and the public of critical information they are entitled to receive under the statute.

Reporting under the statute	Reporting under the proposed rule
10 ppm cadmium in Brand X, train set Y or 10 ppm cadmium in the paint of Brand X, train set Y	10 ppm cadmium in the paint of a car/train set (nonpowered)
10 ppm phthalates in rubber ducky X or 10 ppm phthalates in the coating of rubber ducky X	10 ppm phthalates in the coating of a bath toy
10 ppm phthalates in Brand X, doll Y or 10 ppm phthalates in the substrate of Brand X, doll Y	10 ppm phthalates in the substrate of doll/soft toy (nonpowered)

We wholeheartedly support the Children's Safe Products Act and the requirement that manufacturers disclose the amount of chemicals in their products. But we do not support the provisions in the proposed rule that require reporting by product category. As explained below, Ecology's decision not to require reporting by product is not only bad policy, it is unlawful.

I. Providing the public with information on chemicals in particular children's products will improve children's health and safety.

Providing the public with data on the concentration of CHCCs in particular children's products will enable various stakeholders to assess product safety and make informed choices when purchasing children's products. If the annual report discloses the concentration of CHCCs in particular products, consumers can readily distinguish between products based on the concentration of CHCCs. The annual report can facilitate market demand for safer children's products, but only if consumers have information on chemicals in particular products.

In its comments on the original proposed rule, the Washington Department of Health (“DOH”) emphasized that requiring reporting by particular product will enable consumers to play a role in ensuring the safety of children's products. “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.” Letter from Maryanne Guichard, Assistant Secretary, Washington Department of Health, to John Williams,

¹ The examples provided in the table are purely hypothetical and designed for the sole purpose of illustrating the differences between reporting under the statute and under the proposed rule. These examples are not meant to imply that any products or classes of products mentioned actually contain chemicals of high concern to children.

Washington Department of Ecology (Jan. 7, 2010) at 4.

As DOH noted, providing the public with information on the concentration of CHCCs in the components of product categories may cause consumers to avoid entire product categories -- because consumers will not know which particular product or products contain reported levels of CHCCs. If the annual report discloses that a component within a product category contains a concentration of a CHCC that a consumer deems unsafe, the consumer has only two choices: reducing exposure to all products within the product category that contain the component, or simply accepting exposure to a chemical the consumer believes is unsafe. However, if consumers have information on the concentration of CHCCs in particular products, they will not have to make blanket judgments about entire product categories.

Agencies, organizations, and researchers would also benefit from access to information on the concentration of CHCCs in particular products, because product specific information will improve exposure analyses. In recommending that each annual report disclose the specific product or products containing a CHCC, the Washington Department of Health noted that "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." *Id.* at 2.

In short, stakeholders are best able to assess product safety and make informed purchases if they know the concentration of CHCCs in particular products. Ecology's proposed decision to allow reporting by product category will deprive agencies and the public of product specific information critical to improving the safety of children's products.

II. Ecology has no legal authority to override the legislature's decision to require the annual report to contain information on chemicals in identifiable products.

It is a basic tenet of administrative law that an agency cannot issue a rule that conflicts with the governing statute. *See, e.g., Waste Mgmt. of Seattle, Inc. v. Util. & Transp. Comm'n*, 123 Wash.2d 621, 628, 869 P.2d 1034 (1994). While an agency may interpret an ambiguous statutory term, if a statute is clear, an agency may not change its meaning through rulemaking. *Id.* The Children's Safe Products Act requires manufacturers to report the amount of a chemical of high concern to children in each product -- either in the product as a whole or in a component of a particular product. The legislature decided to require reporting by product in order to provide agencies with data on exposure to potentially harmful chemicals and also to provide the public with meaningful information to guide their purchases of children's products. Since the legislature has already resolved this issue, Ecology has no authority to substitute its policy preferences for those of the legislature.

A. The Rule Conflicts with the Plain Meaning of the Statute, Which Requires Manufacturers to Report the Amount of a CHCC in Each Product -- in Either the Product As a Whole or the Product Component.

The CSPA uses the terms “product,” “product component,” and “product category” in different sections of the statute. These terms are not interchangeable, and the legislature's careful use of terms was not arbitrary.

Section 4 of the CSPA requires the Department of Ecology to submit a report to the legislature on chemicals of concern to children and “children's products or product categories” that might contain such chemicals. RCW 70.240.030(3). The report, which Ecology submitted in July 2009, was required to include policy options for addressing children's products that might contain potentially harmful levels of certain chemicals. The legislature stated the purpose of this report -- to provide the legislature with “policy options for addressing children's products that contain chemicals of high concern for children.” RCW 70.240.030(3).

Section 5 of the CSPA requires manufacturers to submit annual reports to the Department of Ecology which specify the amount of CHCC in each “product or product component.” RCW 70.240.040(4). Section 5 requires the annual report to include six items; each of these six items requires information on either the product or product component. In contrast to section 4, section 5 of the CSPA does not use the phrase product category or product categories.

The legislature specified in great detail the six items that must be included in the annual notice, and the legislature nowhere used the phrase product category in any of those six items. Nonetheless, Ecology has decided that reporting should be done by product category rather than by product. Ecology's rule has systematically shifted the relevant unit of reporting from the product to the product category. Below is a table comparing the relevant language of the statute with the proposed rule.

Statutory requirement	Rule requirement
“A brief description of the <i>product or product component</i> containing the substance;” RCW 70.240.040(2)	“The <i>product category or categories</i> in which it occurs.” WAC 173-334-080(b) “The <i>product component or components within each product category</i> in which it occurs.” WAC 173-334-080(c).
“A description of the function of the chemical in the <i>product</i> ;” RCW 70.240.040(2)	“A brief description of the function, if any, of the CHCC in each <i>product component within each product category</i> .” WAC 173-334-080(d).
“The amount of the chemical used in each unit of the <i>product or product component</i> .”	“The total amount of the CHCC by weight contained in each <i>product component within each product category</i> .” WAC 173-334-080(e)

Section 5 of the CSPA specifies the contents of the annual report. The Act requires that the annual reports contain the amount of a CHCC in each product -- the amount in "each unit of the product or product component." RCW 70.240.040(4). Ecology cannot rewrite the statute by substituting "product component within each product category." Since the rule conflicts with the plain language of the statute, this provision of the proposed rule would be invalid.

B. The Rule Undermines the Statutory Authority Provided to the Department Of Health to Educate Consumers on Chemicals in Children's Products.

Section 6 of the CSPA "authorizes the secretary [of the Department of Health] to establish and maintain a product safety education campaign to promote greater awareness of products designed to be used by infants and children that: . . . Contain chemicals of high concern for children as identified under section 4 of this act." RCW 43.70.660(1)(d). If the secretary conducts such an education campaign, it must be designed to educate, among other people, "parents, foster parents, and other caregivers." RCW 43.70.660(2).

Section 6 of the CSPA authorizes the Department of Health to educate consumers about "products" that contain chemicals of high concern. If the annual reports do not contain information on CHCC in particular products, the Department of Health cannot exercise its authority to educate consumers on chemicals of high concern in products. Section 6 furnishes additional evidence that the legislature required manufacturers to report the presence of CHCC in particular products -- not in product categories.

The Department of Health made precisely this point in its comments on the original proposed rule. The Department of Health stated that:

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.

Letter from Maryanne Guichard, Assistant Secretary, Washington Department of Health, to John Williams, Washington Department of Ecology (Jan. 7, 2010) at 3.

In short, Ecology's interpretation that section 5 permits reporting by product category conflicts with section 6's grant of authority to the Department of Health to educate consumers on CHCC in products. Since the statute must be interpreted to give effect to each section, Ecology's interpretation would be invalid. *See generally Cobra Roofing Serv., Inc. v. State Dep't of Labor & Indus.*, 157 Wash.2d 90, 99, 135 P.3d 913 (2006) ("Statutes must be interpreted and construed so that all the language used is given effect, with no portion rendered meaningless or superfluous.").

C. The Rule Conflicts with One of the Central Strategies of the Statute, Which Is to Provide Consumers with Information on Chemicals in Children's Products.

As the title of the Act suggests, the purpose of the Children's Safe Products Act is to improve the safety of children's products. To achieve that purpose, the law provides for information to be provided to the legislature, agencies, and consumers. In doing so, the CSPA has at least two broad strategies for ensuring safe children's products: on the one hand, providing policymakers with information critical to regulating chemicals, and, on the other hand, providing consumers with information critical to making informed choices about products. These strategies are complementary.

The importance of enabling consumers to make informed choices about children's products runs throughout the Act. In its report to the legislature, Ecology was required to include "recommendations for additional ways to inform consumers about toxic chemicals in products, such as labeling." RCW 70.240.030(3). In section 6 of the Act, the legislature authorized the Department of Health to "establish and maintain a product safety education campaign to promote greater awareness of products designed to be used by infants and children that: . . . Contain chemicals of high concern for children." RCW 43.70.660(1)(d).

In addition to the plain text of the statute, the legislative history indicates the legislature's intent that the annual reports provide consumers with information on particular products. Senator Holmquist offered amendment 282, which would have removed entirely section 5, which contains the annual reporting requirement. The amendment failed. In opposing the amendment, Senator Rockefeller stated:

. . . I would urge members to reject this amendment. This strikes at the very heart of a critical part of the bill which is to provide consumers with information regarding chemicals of major concern. If the manufacturers are not going to be reporting it under this amendment then there's no basis for the information to be disseminated to the public at large. It chokes off the flow of information that I think is essential to our consumers as they make choices about what toys to purchase. Please vote no.

Senate debate, March 3, 2008.

The legislature made a policy decision that both policymakers and consumers have a role to play in improving the safety of children's products. Ecology lacks legal authority to elevate its policy preferences over those of the legislature. The only interpretation of the law that is consistent with the plain meaning and purpose of the Act is that consumers are entitled to receive information on the amount of chemicals in products -- discrete, identifiable products. The agency's proposed interpretation of the statute would prevent consumers from receiving information on chemicals in products, and this interpretation would be invalid.

Conclusion

We appreciate the years of hard work that have gone into the reporting rule. The success of the rule depends in part on whether agencies and the public have information on the amount of CHCCs in particular products. In order to avoid identifying the particular products that contain a chemical of high concern to children, Ecology is proposing to allow reporting by product category rather than by product. We urge the Department to bring the rule in line with sound public policy and in line with the text and purpose of the statute. The final rule should require the annual report to contain the amount of the chemical used in each product -- either in "each unit of the product or product component."

Sincerely,



Matthew Gerhart

Earthjustice

705 Second Ave., Suite 203

Seattle, WA 98104

(206)-343-7340 ext. 1024

(206)-343-1526 [FAX]

mgerhart@earthjustice.org

On behalf of the Washington Toxics Coalition

Grice, Joshua (ECY)

From: Gulledge, Bill [Bill_Gulledge@americanchemistry.com]
Sent: Tuesday, June 14, 2011 1:08 PM
To: Williams, John (ECY)
Cc: Osman-Sypher, Sahar; Shestek, Tim; Kolarik, Emily; Simon, Robert; Matthews, Jordan
Subject: Comments from the ACC Vinyl Chloride Health Committee- Children's Safe Products Reporting Rule
Attachments: VCHC Comments on WA Reporting Rule.pdf

Good Afternoon John:

Attached are the comments from ACC's Vinyl Chloride Health Committee. The comments specifically address the proposed listing of vinyl chloride. ACC's comments on the proposed regulation will be submitted separately. Thank you.

Bill

Bill Gulledge – Chemical Products and Technology Division

bill_gulledge@americanchemistry.com

American Chemistry Council | 700 – 2nd Street NE | Washington, DC | 20002

O: (202) 249-6714 |

www.americanchemistry.com

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June 14, 2011

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

Re: Children's Safe Products Act – Reporting Rule

Dear Mr. Williams:

The Washington Department of Ecology recently invited public comment on its Children's Safe Products Act – Reporting Rule. One of the listed chemicals is vinyl chloride. The Vinyl Chloride Health Committee (VCHC) of the American Chemistry Council represents the U.S. manufacturers of vinyl chloride.¹ The VCHC is pleased to offer our comments.

Vinyl chloride is not available to be purchased by consumers. Vinyl chloride is used primarily for the manufacture of polyvinyl chloride (PVC) and other co-polymers, and is nearly consumed during the initial manufacturing process. After vinyl chloride is polymerized to form PVC, the PVC resin is further stripped to remove residual vinyl chloride. The current federal regulatory limits for residual vinyl chloride in the polymer following the stripping process are in 40 CFR 61.64. The limit for residual vinyl chloride in dispersion resins is 2000 ppm, and for all other resins, the limit is 400 ppm. However, actual stripping efficiencies result in residual levels that are below these regulatory limits.

Additional processing occurs as the PVC resin is made into final products such as pipes, packaging materials or children's toys, and during this processing, the residual vinyl concentration is lowered to even more insignificant levels. As a matter of fact, the U.S. Department of Health and Human Services has determined that children are not exposed to significant levels of vinyl chloride in PVC based toys (ToxGuide™ for Vinyl Chloride, <http://www.atsdr.cdc.gov/ToxProfiles/tp.asp?id=282&tid=51>).

In summary, the current limits on residual vinyl chloride in stripped PVC are effective in controlling vinyl chloride in finished goods to levels deemed insignificant. Furthermore, the proposed national emission standard could result in even lower limits. Therefore, due to the very limited risk of adverse impact from finished PVC products, the VCHC strongly recommends removing vinyl chloride from the list of chemicals in WAC 173-334-130.

¹ Members of the VCHC include: Occidental Chemical Corporation, Georgia Gulf Corporation, PPG Industries, Dow Chemical Company, and Formosa Plastics Corporation





Please contact me at (202) 249-6714 or bill.gulledge@americanchemistry.com if you would like additional information in support of these comments.

Sincerely,

A handwritten signature in black ink that reads "Bill Gulledge". The signature is fluid and cursive, with a long horizontal line extending to the right.

Bill Gulledge
Senior Director, Chemical Products & Technology Division



Grice, Joshua (ECY)

From: Hackman, Andy [ahackman@toyassociation.org]
Sent: Wednesday, June 15, 2011 2:56 PM
To: Williams, John (ECY)
Cc: Gregorich, Joe
Subject: TIA Comments Proposed CSPA Rule - June 2011
Attachments: TIA Comments on CSPA Rule June 2011 - FNL.pdf

Importance: High

Dear Mr. Williams,

Attached please find comments from the Toy Industry Association on the Department of Ecology's Children's Safe Products Act Proposed Reporting Rule. TIA appreciates this opportunity to provide comment applauds the hard work of the Department staff to outreach to impacted stakeholders. TIA looks forward to working with you and DoE staff in helping to implement a workable final regulatory proposal.

Please let me know if you receive the attached comments or have any difficulty opening the file. We look forward to continuing to work with you on this challenging program.

Respectfully submitted,

Andrew Hackman
Senior Director of State Government Affairs
Toy Industry Association, Inc.
1115 Broadway, Suite 400, New York, NY 10010
Tel: 646.520.4851 | Fax 212.633.1429 | Cell: 703.608.2326
Email: ahackman@toyassociation.org | www.toyassociation.org



June 15, 2011

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 173-334 WAC

Dear Mr. Williams,

The Toy Industry Association appreciates this opportunity to provide input on additional issues 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 recognizes that there has been an effort to reach compromise between different viewpoints in these Proposed Regulations and that there has been significant progress to move this proposal forward. TIA looks forward to working with you and DoE staff in helping to implement a workable final regulatory proposal.

TIA is a not-for-profit trade association representing more than five-hundred (500) toymakers, 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. Toy Industry Association and its members have long been leaders in toy safety. In this role, we actively participate in the ASTM Toy Safety Standards Committee which develops safety standards for toys (ASTM F963) in an independent, multi-stakeholder forum, along with industry, government, consumer organizations, engineers, and medical and child development experts. ASTM's risk-based standards are widely recognized and used as models around the globe. Toy safety is a top priority for the toy industry and this mission includes educating industry on conformance with these standards, and parents and caregivers on choosing appropriate toys and ensuring safe play.

These comments incorporate by reference TIA's comments of January 6, 2011 on the Proposed Rule, and comments of August 17, 2010 on the Preliminary Rule. TIA's previous comments raised many concerns that have not been resolved in the current Proposed Rule. Just a few of these concerns include: international trigger level conformity with 0.1%; the inequity of reporting by a company's size – regardless of exposure; the need to apply of the trigger level to a product by total weight, and data concerns for selection of Chemicals of High Concern to Children (CHCC). TIA continues to note these key issues via reference herein. In these comments, we would like to highlight new concerns and clarifications that we would like to request 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:

TIA Comments on Proposed Rule
173-334 WAC
June 15, 2011

1. Practical Quantification Limit (PQL) (WAC 173-334-040 & WAC 173-334-080)

TIA understands that a PQL for each chemical and product application could be different; thus the Department and manufacturers need flexibility in determining what is appropriate for specific products. However today, detectable levels for some chemicals are in the parts per billion, parts per trillion, or even parts per quadrillion level. Therefore, setting the lowest reporting level for an intentionally added ingredient in a range from the PQL to 100 ppm could be extremely challenging to implement. TIA understands from communications with the Department that it is not the intent of the Rule to require vast amounts of new testing to reach a detailed PQL measurement. However, the current language leaves it an open question; as to the depths of analysis and documentation a company or laboratory would need to provide to be defensible and in compliance with the PQL provisions of the Proposed Rule.

TIA requests that the Department provide a guidance document to clarify what typical analysis and testing procedures would meet the definition of PQL and provide some benchmarks for specific chemicals and products; as experience in under this Rule grows.

2. Reporting of Intentionally Added Chemicals & Contaminants (WAC 173-334-080)

Per TIA's earlier comments, we believe that reporting under this Rule should be limited to only intentionally added ingredients. In fact, the concept of focusing on the intentionally added ingredients is supported by the Washington State Department of Health (DoH)/University of Washington Report, dated 23 July 2010, submitted to the DoE (Task 1, C; page 4). Focusing the rule on intentionally added ingredients is necessary because contaminants are not intentionally added to impart a characteristic to a product, and therefore, cannot necessarily be controlled during the manufacture of a product. Contaminants could be found on a product after it leaves control of the manufacturer, so it would be impossible for a manufacturer to report their presence.

As TIA has suggested in earlier comments, a 0.1% threshold is internationally recognized as an acceptable level for delineating between intentionally added chemicals and contaminants. Thus, TIA still believes that this level is justifiable as a trigger level in the Rule. TIA understands that the current Proposed Rule attempts to take into consideration concerns about significant product contamination that might pose a threat to children's health. However, TIA asserts that the 100 ppm threshold is arbitrarily low and in divergence with international standards, which resoundingly endorse 0.1% as a trigger *de minimis* level applied to the total weight of a product.

However, if reporting of contaminants must occur, TIA supports the provision that a manufacturer need not report a contaminant if a due diligence system is in place to minimize the presence of a contaminant. Per our comments below, we look forward to working with the Department on implementing guidance documents that provide clear direction to manufacturers in assuring that the existing due diligence systems (used widely within the toy industry) can be easily understood and acknowledged by the Department.

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3. Change in Product Components Reporting (WAC 173-334-100)

TIA is seeking clarity about when changes in product components in a particular product category, will require notification. Under the proposed language of the Rule, it would seem that there would only be a need to notify the department of a change in the range that was reported, not regarding a specific component of a product. TIA requests that the Department provide additional clarity with regard to how changes to a product or component would be reported.

4. Tier 4 Reporting Language (WAC 173-334-110 (4)(d))

TIA appreciates that chemicals in inaccessible components are exempt from disclosure unless the Department, on case-by-case approach, amends the Rule to require disclosure. However due to technical drafting issues, the current language in the Rule could result in ambiguity as to whether the Department must *first* make a case-by-case determination before a component is considered a Tier 4 component. TIA would like to suggest the following language to provide clearer direction as to how Tier 4 components would be considered.

Tier 4 – children’s product components that during reasonably foreseeable use and abuse of the product would not come into direct contact with the child’s skin or mouth (e.g., inaccessible internal components for all children’s products). ~~Any Reporting requirements for Tier 4 components will not be required, except be based on a case-by-case evaluation by the department and may be required by amendment of these rules, based on a case-by-case evaluation by the department.~~

5. Enforcement WAC 173-334-120

TIA is concerned about ambiguities in the Enforcement section that could result in numerous violations being assessed against a manufacturer for a single product, particularly if the department evaluates chemical content of components at very low levels. A violation should be tied to the applicable product within a category subject to reporting. Since it is the product category, company size, and exposure tier from a product that triggers reporting; a violation should be applied per product in a category subject to reporting. The penalty would be \$5000 for first offense and \$10,000 for each repeat offense. What is deemed a single offense is important; therefore, TIA suggests the following changes to this Section:

(5) A single violation ~~may consist~~ consists of a manufacturer failing to provide the required notice for the presence and accurate amount within the reported range of each CHCC, in each applicable product category, in each applicable product component.

6. Phthalate Reporting Inconsistent with Federal Law (WAC 173-334-140):

TIA is concerned that with the addition of six phthalates to the Chemicals of High Concern to Children; the Rule attempts to regulate in a manner that is inconsistent with federal law, by applying different reporting levels than those sanctioned by CPSC for phthalate restrictions and applied to address the same risk of exposure from toys and child care articles.

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Specifically, under the Consumer Product Safety Improvement Act of 2008 (CPSIA) three phthalates, DEHP, DBP, and BBP, have been permanently prohibited by Congress in concentration of more than 0.1% in “children’s toys” or “child care articles.” In addition, phthalates DINP, DIDP, and DnOP, have been prohibited pending further study and review by a group of outside experts and the CPSC. This interim prohibition applies to child care articles or toys that can be placed in a child’s mouth or brought to the mouth and kept in the mouth so that it can be sucked or chewed that contains a concentration of more than 0.1% of these latter three phthalates¹.

Inclusion of reporting for all six of these phthalates is inconsistent with the regulatory scheme of the CPSC for these substances. Specifically, 15 U.S.C. 2075 provides as follows: “*Whenever a consumer product safety standard under this chapter is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.*”

TIA believes that if reporting is required for these chemicals, the threshold of 0.1% for products must be adopted in this special case, since there is existing federal regulation sanctioning this level and addressing the same risk of exposure (injury) concerns that are the foundation of Washington State’s CSPA.

Additionally, we have not seen evidence of a new or revised evaluation process which would lead to the addition of these specific substances in comparison to the previous version of the list. While a version of the CHCC list from well over a year ago (January 2010) did include several of these phthalates, they subsequently were deleted by the Department (correctly, we believe). In our previous comments TIA has provided support for the proposition that a number of chemicals on the list do not rise to the level of significant risk according to the Department’s selection matrix, based on our interpretation and documented critique of the matrix process and our discussions with Dr. Karr. We continue to assert that the primary health-based and regulatory goal here should be to focus on those substances that represent the most significant health risks, and we do not believe that the toxicology supports selection of certain chemicals (per TIA’s earlier comments) in many instances. The phthalates added (or reinstated) to the newest list are an example of our ongoing technical concerns in that area.

7. Draft Reporting Guidance Document: Request for Clarity on “Reporting Contaminants and Due Diligence”

TIA requests that the Department provide an additional example addressing “trace impurities in feedstock” and “incompletely reacted chemical mixtures”, per the Proposed Rule. This clarification is necessary to address several real world examples where two chemicals are combined or reacted to make a benign finished material; however some trace amount of material from the feedstock remains in the final product.

¹ U.S. Consumer Product Safety Commission, CPSIA Section 108: FAQ. See: <http://www.cpsc.gov/about/cpsia/fag/108faq.html>

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Specifically, TIA suggests the following example to address this in the “Reporting Contaminants and Due Diligence” document:

Example 3: A manufacturer is making a material to be molded into a plastic toy. Chemical A is combined with Chemical B to make plastic material C that has essential properties needed to produce the plastic toy. Some trace amounts of Chemicals A and B remain in plastic material C. Chemicals A and B would be considered contaminants, per the definition in WAC 173-334-040. The manufacturer has one of two options:

- 1) Report the presence of Chemicals A and B if their concentrations individually are above 100 ppm.**
- 2) Rely on the manufacturer’s ability to demonstrate to the agency that a manufacturing control and due diligence program was in place that minimized the presence of Chemicals A and B**

8. Draft Reporting Guidance Document: Request for Clarity on “Product Component”

TIA requests that the Department provide an additional example addressing product components where because of an extremely small sample size it is unrealistic to separate a material for analysis. This situation combines a likely “real-world” situation from Example 5 and Example 7. To illustrate this situation we suggest the following example:

Example 12: A manufacturer makes a miniature shirt for small doll. The shirt is made up of very small pieces of blue and pink fabric. However, there is not enough of the blue and pink fabric in one doll’s shirt to make it reasonable to separate for an acceptable sample size.

Since there is not enough of the blue and pink material for a sample size and it is unrealistic to separate the small pieces of fabric the “doll’s shirt” is considered a single component.

9. 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 reasonable and foreseeable exposure evaluations have been taken into consideration in the development of this Rule. As discussed above, several issues require additional modifications to the Rule and Guidance Documents 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 and Guidance Documents that provide 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 and ahackman@toyassociation.org, or Joseph Gregorich at: 916-454-4281 and

TIA Comments on Proposed Rule
173-334 WAC
June 15, 2011

jgregorich@toyassociation.org if you have any questions or concerns about these comments or would like to discuss in more detail.

Respectfully Submitted,



Andrew Hackman
Senior Director of State Government Affairs



Joseph Gregorich
Director of State Government Affairs



June 13, 2011

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

Dear Administrator John R. Williams Jr.:

RE: The Department of Ecology's Proposal to Identify List of 'Chemicals of High Concern'

The Tri-City Regional Chamber of Commerce, which represents the interests of businesses and organizations within the cities of Kennewick, Pasco, Richland, and West Richland is writing to express our concern about the Department of Ecology's proposal to list six phthalates as 'chemicals of *high concern*' to children as part of the Children's Product Safety Act (CPSA).

This proposed rule is problematic because it conflicts with existing federal law; the Consumer Product Safety Improvement Act (CPSIA) of 2008 already governs the use of phthalates in consumer products. The CPSIA explicitly mandates the preemption of any state or local law that is inconsistent with the Federal standard. Given that a federal preemption exists, this new rule will face immediate legal challenges. This process is a wasteful and unnecessary use of taxpayer resources at a time when Washington State is already financially strapped. It seems unwise for the Department of Ecology to consider regulation that would result in state spending only to be held invalid.

We encourage you to suspend consideration of listing these chemicals as listing is not in the state's best interest. This is counterproductive and would unnecessarily waste state revenue.

On behalf of the Tri-Cities Chamber of Commerce, thank you for your consideration. Please contact me if you have any questions or need any additional information.

Sincerely,

Colin Hastings
Vice President
Tri-City Regional Chamber of Commerce

Grice, Joshua (ECY)

From: Thomas Head [Thomas.Head@wal-mart.com]
Sent: Wednesday, June 15, 2011 11:13 AM
To: Williams, John (ECY)
Cc: Jennifer Kirk; Jennifer Spall; Peggy Fowler; Beth Schommer; Beth Harris
Subject: Walmart's comments to Washington Dept of Ecology on proposed CSPA Rule
Attachments: WM WA DoE CSPA Rule Comments 6-15-2011.pdf

John,
Please accept the attached comments for Walmart on the Department's proposed rule. We appreciate the opportunity to provide feedback. As always, don't hesitate to contact me directly with any questions you may have.

Thank you,

Thomas Head
Product Safety & Regulatory Compliance
Phone 479.204.8976 Fax 479.204.9557
thomas.head@wal-mart.com

Walmart
508 SW 8th Street, MS 0505
Bentonville, AR 72712-0505

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 *****



Product Safety & Regulatory Compliance

Thomas R. Head
508 SW 8th Street
Bentonville, AR 72716
Phone 479.204.8976
Fax 479.204.9557
www.walmart.com

June 15, 2011

submitted via email: john.williams@ecy.wa.gov

John Williams
Department of Ecology
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.

173-334-040 Definitions

We support the definitions provided within this section as written.

173-334-060 Revision of the CHCC List

We support the proposed frequency of revision of the CHCC list and understand the Administrative Procedure Act provides for public comment periods on each chemical introduced.

173-334-80 Notice Requirements

Subsections (1)(b) and (1)(c) should be combined for clarity or in the alternative: subsection (b) should specify a "known" or "likely" contaminant present above 100 ppm.

We support the Department's approach in section (2)(e) to collect information on CHCCs at a component level. As noted in our previous comments, it is unnecessarily difficult to aggregate concentration values in complex products.

173-334-110 Reporting Schedule

We support the Department's approach to the schedule, definition of manufacturers, and four tier systems presented in section 173-334-110 to provide notice on children's products that contain a chemical on the CHCC list.

We recommend further clarification on the four tiers specifically Tier 1 and Tier 2. It is unclear whether each brick is exclusive to one of the four tiers or whether classification is contingent on characteristics of product components meaning a brick could be reported under multiple tiers. For example, it is difficult to determine how a complex product such as a seasonal costume with face make-up component should be classified. The practical approach is to make bricks be exclusive to the Tiers during the initial implementation phases of the first few years. Relying on the GPC brick description regardless of variable components provides clarity essential to information collection efforts across the broad spectrum of potential products to be reviewed for reporting.

Subsection (5) is unclear because it contains references to safer alternatives assessments that are not defined in the rule. The Department should consider removing subsection 5. However, the rule should provide the department with discretion to grant an extension of time to a manufacturer requesting additional time to report a specific product category and address unforeseen issues that will arise during initial phases of reporting. The criteria for requesting the extension of time to the department should be outlined within administrative guidance documents provided on this rule as issues are identified going forward.

173-334-130(3) Enforcement (evidence of due diligence)

As we noted in previous comments, 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 fails to acknowledge differences in due diligence standards for importers and private brand owners that are responsible entities without direct knowledge or control of day to day operations.

Sincerely,

Thomas Head

Grice, Joshua (ECY)

From: Hentges, Steve [Steve_Hentges@americanchemistry.com]
Sent: Wednesday, June 15, 2011 2:24 PM
To: Williams, John (ECY)
Subject: Comments on Children's Safe Products - Reporting Rule - Supplemental Filing
Attachments: CSPA Reporting Rule Supplemental Comments - PC-BPA.pdf

Dear Mr. Williams,

Please find attached comments from the Polycarbonate/BPA Global Group on the Children's Safe Products – Reporting Rule – Supplemental Filing. Our comments are primarily 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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June 15, 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)
– Supplemental Filing

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) supplemental filing. 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 are primarily focused on the inclusion of bisphenol A on the list of chemicals of high concern to children and are complementary to general comments from ACC on the proposed rule that have been submitted separately. As described in our attached comments, the weight of scientific evidence indicates that bisphenol A does not clearly meet the

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.

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.

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,

A handwritten signature in black ink, appearing to read 'S G Hentges', with a long horizontal line extending to the right.

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

June 15, 2011

1. Description of Food-Related Products Regulated by FDA Should Be Clarified

In response to previous comments, we note that the revised reporting rule now specifies that “‘children’s product’ does not include over the counter drugs, prescription drugs, food, dietary supplements, packaging, medical devices, or products that are both a cosmetic and a drug regulated by the Food and Drug Administration” (emphasis added). As noted in Ecology’s response to comments, the law already exempts these products.

We assume that the listing of “packaging” is intended to reflect the exemption for “food packaging” provided in the underlying law. Strictly speaking though, FDA regulates food–contact materials used to make food packaging rather than specific food packaging articles. In FDA’s regulatory scheme, food-contact materials are regulated as food additives.

For consistency between Ecology’s and FDA’s regulatory language, and to avoid any uncertainty about which FDA-regulated products are exempted, we recommend a slight modification to the list of exempted products. In place of the separated listings for “food” and “packaging,” we propose a single combined listing of “food, food additives, and food-contact materials (including food packaging materials).”

The inclusion of food additives and food-contact materials would be consistent with legislative intent since these are the FDA-regulated materials used to make food packaging, which is specifically mentioned in the underlying law.

2. Bisphenol A Does Not Clearly Meet the Children’s Safe Products Act Standard for a “High Priority Chemical” and Should Be Removed from the Reporting List

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

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.

(BPA) 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.

In our previous comments dated January 7, 2011, we provided extensive documentation to demonstrate that Ecology’s three-phase process to screen chemicals did not meet the strict regulatory standard to designate BPA as a high priority chemical. In response to comments, Ecology noted that a more thorough review of each chemical was conducted in Phase III, the results of which are now documented in summary form on Ecology’s website. The relevant part of that summary on toxicity for BPA is included below.²

“Bisphenol A causes reproductive and developmental toxicity in laboratory animals at high doses.^{3,4,5} At low doses that are similar to estimated exposures in people, bisphenol A can affect the developing rodent brain and behavior, prostate and mammary gland development, and cause early onset of puberty in females.³ There is wide variability in reported results from studies at low doses.^{3,4,5}”

Two of the citations in this summary, however, are assessments that do not reach conclusions based on the regulatory standard applicable to the Children’s Safe Products – Reporting Rule.^{3,4} Merely citing these reviews does not demonstrate that BPA meets the regulatory standard. We assume instead that these citations are intended to point to comprehensive sources of “credible scientific evidence” that supports a conclusion that BPA is “known to” cause the effects listed in the summary above. The third citation refers to a review that provides scientific input into a regulatory process that uses a similar standard,⁵ but does not provide the conclusion of that regulatory process. As further documented below, these three citations neither individually nor collectively meet the regulatory standard to designate BPA as a priority chemical.

A. The Term “Known To” Denotes a High Degree of Certainty

The regulatory standard that must be met to designate BPA as a priority chemical requires that BPA is “known to” cause one of the listed toxic effects. Although the term “known to” is not specifically defined, in its established meaning the term denotes a high degree of certainty. Consistent with this, schemes that categorize chemicals for their potential to cause certain health effects use the term “known to” or a similar term (e.g., “clearly shown” under California

² Taken from <http://www.ecy.wa.gov/programs/swfa/cspa/pdf/80057.pdf>.

³ US Department of Health and Human Services, National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction (CERHR) Monograph on the potential human reproductive and developmental effects of Bisphenol A. September 2008. <http://cerhr.niehs.nih.gov/evals/bisphenol/bisphenol.html>.

⁴ European Commission, Joint Research Centre. European Risk Assessment Report: 4,4’isopropylidenediphenol (bisphenol A) Risk Assessment, February 2010. http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/bisphenolareport325.pdf.

⁵ California EPA, Office of Environmental Health Hazard Assessment(OEHHA). Evidence on the developmental and reproductive toxicity of Bisphenol A. October 2009. http://oehha.ca.gov/prop65/CRNR_notices/state_listing/data_callin/pdf/BPA050109.pdf

Proposition 65) to indicate the highest level of certainty. Categories with lower levels of certainty typically use terms such as “probable,” “possible,” or “reasonably anticipated.” The Children’s Safe Product – Reporting Rule could have, but did not, use such terms to indicate that a lower level of certainty is sufficient to meet the standard. Thus, application of the standard to specific chemicals appropriately should require a high degree of certainty.

A second critical aspect related to certainty is that designation of a chemical as a priority chemical should be based on the weight of scientific evidence. Results from a single study should not be relied upon when multiple studies are available with relevant data. Consistent and coherent results from multiple high-quality studies may provide an adequate weight of evidence to support a conclusion with a high degree of certainty. Inconsistent results would generally not be suitable to support a conclusion with a high degree of certainty.

A third critical aspect related to certainty is specificity, which is of particular relevance for reproductive and developmental effects. Some chemicals selectively cause reproductive or developmental effects at doses that do not also cause systemic toxicity. Selective effects found in high-quality studies may be suitable to support a conclusion with a high degree of certainty. Other chemicals cause reproductive or developmental effects only in conjunction with systemic toxicity that results from exposure to high doses. In these cases, the reproductive or developmental effects may be secondary to the systemic toxicity. Because it can be difficult to determine if the reproductive or developmental effects are the result of systemic toxicity or are selective, results from studies that find effects only at high doses in conjunction with significant systemic toxicity are less suitable for reaching a conclusion with high certainty.

B. BPA Is Not “Known To” Cause Reproductive and Developmental Toxicity at High Doses

Without any analysis or citations to specific studies, the summary states that BPA “causes reproductive and developmental toxicity in laboratory animals at high doses.” However, evaluation of the relevant evidence reveals that it is not known with a high degree of certainty that BPA causes reproductive or developmental toxicity.

The most relevant studies to assess reproductive and developmental toxicity at high doses are the standard developmental toxicity studies in rats and mice⁶ and a pair of comprehensive, high-quality multi-generation reproduction studies in rats⁷ and mice.⁸ These studies are discussed in

⁶ Morrissey, R.E., George, J.D., Price, C., Tyl, R.W., Marr, M.C., and Kimmell, C.A. 1987. The developmental toxicity of bisphenol A in rats and mice. *Fundamental and Applied Toxicology*. 8:571-582.

⁷ Tyl, R.W., Myers, C.B., Marr, M.C., Thomas, B.F., Keimowitz, A.R., Brine, D.R., Veselica, M.M., Fail, P.A., Chang, T.Y., Seely, J.C., Joiner, R.L., Butala, J.H., Dimond, S.S., Cagen, S.Z., Shiotsuka, R.N., Stropp, G.D., and Waechter, J.M. 2002. Three-generation reproductive toxicity study of dietary bisphenol A in CD Sprague-Dawley rats. *Toxicological Sciences*. 68:121-146.

⁸ Tyl, R. W., Myers, C. B., Marr, M. C., Sloan, C. S., Castillo, N. P., Veselica, M. M., Seely, J. C., Dimond, S. S., Van Miller, J. P., Shiotsuka, R. N., Beyer, D., Hentges, S. G., and Waechter, J. M. 2008. Two-generation reproductive toxicity study of dietary bisphenol A (BPA) in CD-1® (Swiss) mice. *Toxicological Sciences*. 104(2):362-384.

each of the documents cited in Ecology's BPA toxicity summary above^{3,4,5} and so will not be summarized here in detail.

As noted in the European Risk Assessment Report⁴, “no evidence that BPA is a developmental toxicant was observed in standard developmental toxicity studies in rats and mice.” In the two multi-generation studies, limited reproductive or developmental effects, inconsistent between the two studies, were observed only in conjunction with significant systemic toxicity. Based on the results from the entire studies, the researchers concluded that “BPA should not be considered a selective reproductive toxicant” in rats,⁷ and “BPA is not considered a selective reproductive or developmental toxicant in mice.”⁸

While the systemic effects in the two multi-generation studies were only mentioned in passing in the NTP report³ (which was primarily focused on low-dose effects), the European Risk Assessment Report⁴ discusses them in more detail. For example, in regard to high dose effects in the rat multi-generation study, the reports states “although this effect was seen only at a dose level causing parental toxicity ... it is not clear whether or not the finding could be a secondary consequence of parental toxicity, or a direct effect of BPA.” If it is not clear whether BPA itself causes reproductive or developmental effects, or whether the observed effects are secondary to parental toxicity, it cannot be concluded with any certainty that BPA is “known to” cause reproductive or developmental effects.

As discussed in our previous comments, the issue of systemic toxicity and effects at high doses was also addressed by an expert committee (Developmental and Reproductive Toxicant Identification Committee) that evaluated all relevant studies to determine whether BPA should be listed as a reproductive or developmental toxicant under California's Proposition 65. The materials reviewed by the committee principally included the three documents^{3,4,5} cited in Ecology's short summary on BPA along with the specific studies described in these documents. Based on their own scientific review of these materials, and explicitly in consideration of systemic toxicity at high doses, the committee voted unanimously in July 2009 that BPA has not been “clearly shown” to be a reproductive or developmental toxicant. The “clearly shown” standard that is operative in California requires a high level of certainty and is comparable to the “known to” standard that is operative in Washington.

Overall, selective reproductive or developmental effects at high doses have not been determined with any certainty for BPA. The limited and inconsistent effects that have been reported, only in conjunction with significant systemic toxicity, do not provide a sufficient basis to conclude that BPA is “known to” cause reproductive or developmental effects.

C. BPA Is Not “Known To” Cause Reproductive and Developmental Toxicity at Low Doses

Also without any analysis or citations to specific studies, the summary states that “at low doses ... bisphenol A can affect the developing rodent brain and behavior, prostate and mammary gland development, and cause the early onset of puberty in females”. Although this

statement is attributed only to the NTP report³, each of the three documents^{3,4,5} cited in Ecology's summary provide relevant information.

The European Risk Assessment Report⁴ extensively discusses a large number of studies that examined the potential for BPA to cause reproductive or developmental effects at low doses. Overall this report did not find any compelling evidence that BPA is “known to” cause reproductive or developmental effects at low doses. The NOAEL for reproductive and developmental toxicity was set at 50 mg/kg/day, based on high-dose systemic effects in the multi-generation studies discussed above, which clearly indicates that studies reporting effects at low doses were not sufficiently credible to support an overall conclusion to the assessment.

The NTP report³ also extensively discussed the same body of studies on reproductive or developmental effects at low doses. We addressed the NTP report at length in our previous comments, which are incorporated by reference. In short, the conclusions of the NTP report clearly do not indicate that BPA is “known to” cause reproductive or developmental effects. The NTP report pointedly stated in regard to studies that examined low doses of BPA, “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). Based on this limited evidence, the effects listed in Ecology's short toxicity summary were qualitatively designated as “some concern” (effects on the brain, behavior, and prostate gland) or “minimal concern” (effects on the mammary gland and earlier puberty in females). These two concern levels are the third and fourth levels on a five-point scale used by NTP ranging from serious concern, concern, some concern, minimal concern, and negligible concern for adverse effects. For BPA, the NTP report did not reach any conclusions at the top two concern levels. Limited evidence cannot provide the high level of certainty required to conclude that BPA is “known to” cause reproductive or developmental effects.

As noted above in regard to high doses, California's expert committee also reviewed all relevant scientific studies on BPA, including a large number of studies that examined low doses. Consistent with the conclusions of the European Risk Assessment Report and the NTP Report, California's expert committee voted unanimously that BPA has not been “clearly shown” to be a reproductive or developmental toxicant at high or low doses.

Consistent with the views expressed in the three documents cited in Ecology's toxicity summary, it is notable that the summary also states “there is wide variability in reported results from studies at low doses.” It is not apparent how wide variability in results can support a conclusion that BPA is “known to” cause reproductive or developmental effects.

Overall, the conclusions of each of the three documents cited in Ecology's summary are consistent with the views of other government agencies worldwide that have reviewed BPA. Based on extensive scientific evidence, BPA is not “known to” cause reproductive or developmental effects and should be removed from the reporting list.

Grice, Joshua (ECY)

From: Jack, Maia [MJack@gmaonline.org]
Sent: Tuesday, June 14, 2011 9:03 AM
To: Williams, John (ECY)
Cc: Hewitt, John; Phillips, Keith (GOV); Terwilleger, Karen (ECY); Kraege, Carol P. (ECY)
Subject: GMA Comments re WA DoE CSPA Revised Draft Rule
Attachments: 20110614_GMA Comments to WA CSPA REVISED Draft Rule.pdf

Importance: High

Dear Mr. Williams:

GMA appreciates the opportunity to submit these comments in response to Washington Department of Ecology's REVISED Draft Rule to implement its Child Safe Products Act of 2008.

Best,
Maia

Maia M. Jack, Ph.D.

Senior Manager, Science Policy - Chemical Safety

Grocery Manufacturers Association

1350 I Street, NW, Suite 300,

Washington, D.C.,

20005

202-639-5922 Office

202-285-6056 Cell

202-639-5991 Fax

mjack@gmaonline.org



June 14, 2011

John R. Williams

Washington State Department of Ecology

W2R HQ

PO Box 47775

submitted via email: john.williams@ecy.wa.gov

Olympia, WA 98540-7775

Re: Comments on REVISED 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) REVISED draft rule, “Chapter 173-334 WAC Children’s Safe Products – Reporting Rule (May 4, 2011)¹”. This is a follow-up to GMA’s August 13, 2010 and December 31, 2010 comments on the Pilot Rule, which are incorporated here by reference.

Scope AND Intentionally-Added

GMA is supportive of many of the changes that the Washington Department of Ecology (DoE) made to the draft rule. Specifically, clarification on the scope of children’s products helps demarcate which consumer products are impacted by these regulations, allowing the regulated community to know the kinds of products for which reporting is required and to easily comply with reporting of ranges of Chemicals of High Concern to Children (CHCC) in these products. Suggested revision to the draft regulatory text to

¹ http://www.ecy.wa.gov/laws-rules/wac173334/p0904a_supp.pdf

include the concept of “intentionally-added” helps ensure that the focus of this program is on CHCC that may be intentionally-added to have an intended function in the final product, and for which product manufacturers are directly responsible.

Relevant Data Sources AND Credible Scientific Evidence

However, GMA maintains that some of the data sources and approaches used in populating CHCC list are inappropriate and not relevant to Washingtonians. (*Please see* GMA comments dated August 13 and December 31, 2010.) The reliance on non-US information (Danish, Dutch, EU) about product uses and exposures is not reflective of actual product use by and exposure to Washingtonians, nor to the Washington environment. Additionally, “credible” peer-reviewed scientific literature (in sections WAC 173-334-070 (4)(c) AND WAC 173-334-080 (1) and (2) of the draft rule) ought to be clearly defined and include some notion of reliability.

“Credible” peer-reviewed scientific literature. Study results which have undergone independent scientific peer review of experimental design and study conduct that are reliable², adequate, and relevant to human health and the environment resulting in publication in a peer-reviewed journal or publication by an authoritative federal or international governmental agency, including but not limited to the U.S. National Toxicology Program, U.S. Federal Drug Administration, U.S. Environmental Protection Agency, U.S. Centers for Disease Control and Prevention, World Health Organization, or the European Chemicals Agency.

Reporting Ranges

Reporting ranges should begin at levels above a 0.1% *de minimis* threshold, rather than from the Practical Quantification Limit (PQL).

De minimis provisions are standard in a variety of chemical and product safety laws:

- (i) Europe’s REACH chemical law applies a 0.1% *de minimis* level as a default in products. REACH’s 0.1% *de minimis* applies broadly, even to designated Substances of Very High Concern that become banned in Europe.
- (ii) The European cosmetic law also includes a 0.1% *de minimis* level for carcinogens and reproductive toxicants.
- (iii) This same level is also used in worker and transportation regulations in Europe and North America. The European Classification, Labelling and Packaging (CLP) law, which addresses over 3000 hazardous substances, contains a 0.1% *de minimis* default. The law also allows European authorities

² 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 and sets acceptability criteria. 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) is 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)

the flexibility to scientifically adjust the *de minimis* lower or higher on the basis of likelihood of harm.

Establishing a 0.1% *de minimis* is consistent with other national and international laws and should be adopted.

Reporting should also be limited to CHCCs that are intentionally-added ingredients for which product manufacturers have direct knowledge of how much is ADDED to/USED in an implicated product. **Regarding contaminants, product manufacturers might be reasonably expected to know about presence of a select few CHCCs that are contaminants based on existing standards, raw material specifications, and federal regulations.** *To essentially require testing for the possible presence of ALL listed CHCCs (i.e., 66 substances) in each implicated product is unreasonable, impractical, and highly burdensome, and without justification of a concurrent consumer or public health benefit.*

Confidential Business Information

GMA urges that provisions in the revised draft rule adequately protect Confidential Business Information (CBI) and not disclose proprietary information regarding use levels, function, and company name and/or brand to competitors. It is critically important to ensure that submitted CBI is in fact protected from release. The Department should develop strong procedures so that submitters can be certain that their trade secret information will be adequately protected.

GMA appreciates the 45-day notice that the Department affords manufacturers to respond to specific inquiries (prior to further action by the Department) should an unreported CHCC be found in an implicated product:

- (i) As GMA understands, if the CHCC is a contaminant in the implicated product above 100 ppm and the manufacturer provides adequate justification by demonstrating the existence of a “manufacturing control program” and “due diligence”, then this information will NOT be disclosed to the public OR posted on the website.
- (ii) Additionally, regarding implicated “promotional items” that are packaged with exempt-products, should there be specific inquiries as to CHCC in the promotional item, GMA understands that the product manufacturer will be given 45-days to inform its supplier of the promotional item and the Department that the supplier is the appropriate entity responsible for reporting on CHCCs in the promotional item, per Washington’s Children’s Safe Products Reporting Rule. The name of the downstream product manufacturer that packages the implicated promotional item with its exempt-product would not be disclosed along with the information on CHCCs in the promotional item.

GMA is committed to assisting the Department in developing a credible and workable green chemistry program that will achieve Washington's objective set out in its Children's Safe Products Act of 2008. 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,

A handwritten signature in blue ink, appearing to read "John Hewitt".

John Hewitt
Director, State Affairs
Grocery Manufacturers Association
1215 K Street, Suite 1500
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

Grice, Joshua (ECY)

From: Cherie Holman [cherieholman@comcast.net]
Sent: Monday, June 13, 2011 7:40 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Cherie Holman
4214-A Evanston Avenue N.
Seattle, WA 98103-7207

Grice, Joshua (ECY)

From: Mark Johnson [mark.johnson@retailassociation.org]
Sent: Wednesday, June 15, 2011 4:15 PM
To: Williams, John (ECY)
Subject: Comments on CSPA Reporting Rules

June 15, 2011

John Williams
Department of Ecology
By email

Dear Mr. Williams:

On behalf of the Washington Retail Association and its members I am writing to comment on the proposed rules Chapter 173-334 Children's Safe Products – Reporting Rule.

I surveyed my members and received the following comments.

Comments from member number one:

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.

"Children's product" has the same meaning as defined in RCW 70.240.010.

(a) For the purposes of this rule, children's products only include products that are sold, or are to be offered for sale, to consumers in the state of Washington.

(b) In addition to the exemptions specified in RCW 70.240.010, for the purposes of this rule, "children's product" does not include over the counter drugs, prescription drugs, food, dietary supplements, packaging, medical devices, or products that are both a cosmetic and a drug regulated by the Food and Drug Administration.

(c) A product label that includes usage instructions for use of a product that apply to children does not in and of itself establish that the product is a children's product.

"Contaminant" means trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. They can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products.

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

"Intentionally added chemical" means a chemical in a product that serves an intended function in the product component.

"Manufacturer" means the producer, importer, or wholesale domestic distributor of a children's product and is more specifically defined in RCW 70.240.010. For the purposes of this rule, a retailer of a children's product is not a manufacturer unless it is also the producer, manufacturer, importer, or domestic distributor of the product.

"Mouthable" means able to be brought to the mouth and kept in [3] OTS-3630.6 the mouth by a child so that it can be sucked and chewed. If the product can only be licked, it is not able to be placed in the mouth. If a product or part of a product in one dimension is smaller than five centimeters, it can be placed in the mouth.

"Practical quantification limit (PQL)" means 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. The value for a given chemical could be different depending on the matrix and the analytical method used.

"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.

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

Comments:

Proposed additional definitions to include:

"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 173-334-090 Who is required to provide notice to the department?

(1) The manufacturer of a children's product, 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 following hierarchy will determine which person or entity the department will hold primarily responsible for ensuring that the department receives a complete, accurate, and timely 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.~~

Comments:

New proposed Section 3:

(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.

Comments from member number two:

Scope AND Intentionally-Added

We are supportive of many of the changes that the Washington Department of Ecology (DoE) made to the draft rule. Specifically, clarification on the scope of children's products helps demarcate which consumer products are impacted by these regulations, allowing the regulated community to know the kinds of products for which reporting is required and to easily comply with reporting of ranges of Chemicals of High Concern to Children (CHCC) in these products. Suggested revision to the draft regulatory text to include the concept of "intentionally-added" helps ensure that the focus of this program is on CHCC that may be intentionally-added to have an intended function in the final product, and for which product manufacturers are directly responsible.

Relevant Data Sources AND Credible Scientific Evidence

However, we maintain that some of the data sources and approaches used in populating CHCC list are inappropriate and not relevant to Washingtonians. The reliance on non-US information (Danish, Dutch, EU) about product uses and exposures is not reflective of actual product use by and exposure to Washingtonians, nor to the Washington environment. Additionally, "credible" peer-reviewed scientific literature (in sections WAC 173-334-070 (4)(c) AND WAC 173-334-080 (1) and (2) of the draft rule) ought to be clearly defined and include some notion of reliability.

"Credible" peer-reviewed scientific literature. Study results which have undergone independent scientific peer review of experimental design and study conduct that are reliable^[1], adequate, and relevant to human health and the environment resulting in publication in a peer-reviewed journal or publication by an authoritative federal or international governmental agency, including but not limited to the U.S. National Toxicology Program, U.S. Federal Drug Administration, U.S. Environmental Protection Agency, U.S. Centers for Disease Control and Prevention, World Health Organization, or the European Chemicals Agency.

Confidential Business Information

We hope provisions in the revised draft rule will adequately protect Confidential Business Information (CBI) and not disclose proprietary information regarding use levels, function, and company name and/or brand to competitors. It is

critically important to ensure that submitted CBI is in fact protected from release. The Department should develop strong procedures so that submitters can be certain that their trade secret information will be adequately protected.

We appreciate the 45-day notice that the Department affords manufacturers to respond to specific inquiries (prior to further action by the Department) should an unreported CHCC be found in an implicated product:

- (i) As we understand, if the CHCC is a contaminant in the implicated product above 100 ppm and the manufacturer provides adequate justification by demonstrating the existence of a “manufacturing control program” and “due diligence”, then this information will NOT be disclosed to the public NOR posted on the website.
- (ii) Additionally, regarding implicated “promotional items” that are packaged with exempt-products, should there be specific inquiries as to CHCC in the promotional item, we understand that the product manufacturer will be given 45-days to inform the Department and its supplier of the promotional item that the supplier is the appropriate entity responsible for reporting on CHCCs in the promotional item per Washington’s Children’s Safe Products Reporting Rule. The name of the downstream product manufacturer that packages the implicated promotional item with its exempt-product would not be disclosed along with the information on CHCCs in the promotional item.

Comments from member number three:

General Principles

- Government efforts to force information into the consumer marketplace should be based on sound scientific fact; the information must be collected and made available to consumers in a context where it can serve a purpose other than instilling consumer fear or distrust of either retailers or regulators.
- All stakeholders – consumers and the regulated community alike – are served best when the requirements are clearly and easily articulated.
- No stakeholder benefits when readers are able to draw different conclusions about what the regulations require. Some of the changes proposed by the Department do not make the rule more easily understood.
- Maine and Minnesota are working on their own lists of chemicals of high concern to children and there is a very real risk that a particular CHCC could be required listing in 1 state but not another. This inconsistent treatment of the same chemical by 2 governmental units will confuse every stakeholder and is exactly contrary to the stated goal of the legislation. WRA should recommend that Washington state go out of its way to not impose requirements on its retailers that are more onerous than those faced by retailers in other states.

Specifics:

- In proposed section 173-334-090, page 6, the Department establishes a hierarchy to determine which of several possible entities it will hold primarily responsible for filing the notice. In (a) the Department has inserted the word “designed”, so that an entity that “designed” a product – whatever that means- is as responsible as the manufacturer for filing the notice. We believe use of this word “designed” is not necessary, will cause confusion and exceeds the Department’s authority under the statute. The statute focuses on entities that produce (manufacture) an item. These entities in the supply chain are primarily responsible for the notice. This makes sense as the manufacturer is in the best position to know what is in the product. The “designer” - the entity that said we want a blue sippy cup no taller than 5 inches – likely will not specify raw materials. But even if it does, as between the state and the manufacturer the state’s interest are best served to look solely to the manufacturer and not to create a new category of regulated entity. We recommend removing the word.
- We agree with distinguishing between added chemicals and contaminants. We agree that raising the reporting trigger from 40 ppm to 100 ppm is a good change. It more closely reflects the current federal requirements under the Consumer Product Safety Improvement Act and thus will avoid a situation where one government says a chemical is not a concern and another says it is.

- The concept of the “practical quantification limit” (PQL) is fatally flawed and places the entire rule at risk of failure. This is because there would be no standard. The words “scientifically defensible, standard analytical methods” provide very little guidance as to what is required. The Department acknowledges this when it states explicitly that “the value for a given chemical could be different depending on the matrix and the analytical method used.” The question is different than what? If we mean different from one manufacturer to another, then we’re simply placing consumer data in Washington state at the mercy of the test equipment manufacturers. We recommend returning to a stated and certain minimum. Maybe 40 ppm. If the test result shows a concentration of 40 ppm or less in the component for the CHCC then it does not have to be listed regardless of where in the range of 0 to 40 ppm that this particular test falls.

Comments from member number four:

We have concerns with the proposed inclusion of phthalates as chemicals of high concern to children in the draft reporting rule for the Children’s Safe Product Act (CPSA). Listing phthalates has potential implications for consumer health and safety.

Our concerns with the draft regulation center on the proposal to list six phthalates (DIDP, DINP, DBP, BBP, and DNoP) as chemicals of high concern to children. Listing phthalates runs counter to findings in government reviews and assessments on the safety of these chemicals.

Phthalates are used in numerous products to make them softer, more flexible and safer and have been in high production usage for several decades.

Various reviews in the United States and overseas speak to the safety of phthalates in their current applications in consumer goods. Among the agencies that have extensively reviewed phthalates are the National Toxicology Program and the U.S. Center for Disease Control and Prevention. The safety record of phthalates, in addition to their effectiveness as plasticizers, are among the main reasons why phthalates are the main plasticizers used in consumer products. Contrary to the conventional wisdom, these chemicals actually enhance our well-being and are vital to our standard of life. For example, phthalates are used extensively for patient care in hospitals as they are core components of various medical components such as blood bags and IVs. Listing these chemicals would put fear ahead of extensive science that has already deemed them safe, and is not in the best interest of the citizens of Washington.

In turn, listing these six phthalates would send a signal to the marketplace that these chemicals are dangerous when in fact they are not. Manufacturers will voluntarily deselect phthalates and replace them with less studied and potentially less effective alternatives which could not only expose consumers to potential harm and injury but also could lead to less effective products and place our members at a competitive disadvantage with products made in other states.

Furthermore, there is already a federal law on the books and listing phthalates would be duplicative of the measures being enforced by federal policymakers and regulators. Back in 2008, the U.S. Congress mandated a uniform federal system of regulation to provide for appropriate regulation of phthalates and to avoid undue intrusions on commerce caused by conflicting state mandates or requirements. This preemption of local and state laws regarding phthalates regulation was included to ensure the safety of all children nationwide and to avoid the chaos created by a state-by-state patchwork of

standards regulations. Pursuing phthalate measures here in Washington that conflict with the federal standard on phthalates would be struck down in court after enactment and end up wasting taxpayer money and state government resources.

We urge the Department of Ecology to reconsider the listing of the six phthalates under the Children's Safe Products Act.

We appreciate this opportunity to submit our suggestions. If you have any questions please feel free to contact me.

Sincerely,

Mark Johnson
Vice President of Government Affairs
Washington Retail Association
360-943-9198 ext 15

^[1] 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 and sets acceptability criteria. 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) is 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)

Grice, Joshua (ECY)

From: Mark Johnson [mark.johnson@retailassociation.org]
Sent: Thursday, June 23, 2011 8:54 AM
To: Williams, John (ECY)
Subject: Clarification on comments submitted on CSPA Proposed Rules

June 23, 2011

Dear Mr. Williams:

My apologies. When I submitted my member's comments on the proposed CSPA Rules I failed to attached the explanation that they provided which is important to understanding their comments. Below please find both their explanation and their proposed changes.

I appreciate your consideration.

Sincerely,

Mark Johnson
Vice President of Government Affairs
Washington Retail Association
360-943-9198 ext 19
360-704-0048 cell

Explanation for the changes:

The proposed rules expand the scope of the statute to include entities who designed the product (but did not actually produce it) and who marketed the product under their trademark – which brings in private label retailers (PLRs). We object to PLRs being subjected to these onerous reporting requirements. PLRs have a very limited role in the supply chain and have no control over the actual production of the product. We also object to the regulations taking away the ability for an importer to rely on its supplier (especially those located overseas) for compliance on these reporting requirements. As with PLRs, importers have no control over the production of a product. Again, the burden of the reporting requirements should fall solely on the “producer” of the product.

The changes below: (1) add definitions to help clarify the definition of “manufacturer” (including that a retailer is not a “distributor”); (2) strike language that attempts to bring in private label retailers; and (3) add language to provide a safe harbor exemption for importers.

Proposed changes:

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.

"Children's product" has the same meaning as defined in RCW 70.240.010.

(a) For the purposes of this rule, children's products only include products that are sold, or are to be offered for sale, to consumers in the state of Washington.

(b) In addition to the exemptions specified in RCW 70.240.010,

(Correction submitted after close of comment period)

Public Comments Received on Supplemental Proposed CSPA Rule

for the purposes of this rule, "children's product" does not include over the counter drugs, prescription drugs, food, dietary supplements, packaging, medical devices, or products that are both a cosmetic and a drug regulated by the Food and Drug Administration.

(c) A product label that includes usage instructions for use of a product that apply to children does not in and of itself establish that the product is a children's product.

"Contaminant" means trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. They can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products.

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

"Intentionally added chemical" means a chemical in a product that serves an intended function in the product component.

"Manufacturer" means the producer, importer, or wholesale domestic distributor of a children's product and is more specifically defined in RCW 70.240.010. For the purposes of this rule, a retailer of a children's product is not a manufacturer unless it is also the producer, manufacturer, importer, or domestic distributor of the product.

"Mouthable" means able to be brought to the mouth and kept in [3] OTS-3630.6 the mouth by a child so that it can be sucked and chewed. If the product can only be licked, it is not able to be placed in the mouth. If a product or part of a product in one dimension is smaller than five centimeters, it can be placed in the mouth.

"Practical quantification limit (PQL)" means 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. The value for a given chemical could be different depending on the matrix and the analytical method used.

"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.

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

Comments:

Proposed additional definitions to include:

"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 173-334-090 Who is required to provide notice to the department?

(Correction submitted after close of comment period)

Public Comments Received on Supplemental Proposed CSPA Rule

(1) The manufacturer of a children's product, 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 following hierarchy will determine which person or entity the department will hold primarily responsible for ensuring that the department receives a complete, accurate, and timely 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.~~

Comments:

New proposed Section 3:

(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.

Grice, Joshua (ECY)

From: Angela Kelly [angiesfemail@yahoo.com]
Sent: Monday, June 13, 2011 5:44 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Angela Kelly
1817 Adams St SE
Olympia, WA 98501

Grice, Joshua (ECY)

From: Gardener [gardener@silkroadenvironmental.com]
Sent: Saturday, May 07, 2011 7:53 PM
To: Williams, John (ECY)
Subject: Childs safe Products proposed regulation

With the budget shortfalls, how long will a manufacturer or importer be required to wait for a Tier IV case by case evaluation?

How many children have been negatively affected in the past that requires us to pass this new law that would not have been banned under Federal Regulations.

This seems to me, a waste of time and money, requiring manufacturers and importers, to jump through another hurdle for our specific market, which is not applicable to neighboring states. So anyone that wants an item that is not available in WA can buy from Oregon or CA. How will this affect large manufacturers like Sony, who must now submit all the game controllers for special testing and reporting by our understaffed state employees.

It does not seem that in this age of high unemployment and decreasing manufacturing capabilities, that we need to impose yet more regulations on the few industries remaining.

I know the rules are noble, but I think the execution will be sloppy, unenforced, and create useless, unread reporting by the manufacturers. The rule even states that the presence of these chemicals does not mean its harmful, It is yet simply another way that the agency and other interested parties, to make manufacturers collect data for them at the manufacturer's cost, because the interested agencies lack the resources or initiative to collect it for themselves. I don't know how many times I have seen these reports that take a lot of time to compile, never read , usually simply opened and stamped that it was received.

There is no measurable goal, or sunset provision if this regulation provides no useful information. There is no additional budget for this new group of government employees to now implement this plan.

Ray Lam
Silk Road Environmental LLC.

Grice, Joshua (ECY)

From: Kerry Logan [bearnecessitys@yahoo.com]
Sent: Tuesday, June 14, 2011 5:44 AM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Kerry Logan
3091 Stemilt Creek Rd
Address Line 2
Wenatchee, WA 98801

Grice, Joshua (ECY)

From: Barbara Losey [blosey@regnet.com]
Sent: Wednesday, June 15, 2011 2:02 PM
To: Williams, John (ECY)
Cc: rfensterheim@regnet.com
Subject: APERC Comments on CSP Rule
Attachments: APERC Comments on WA CSP Rule(06 15.2011).pdf; Attachment 1-APERC Comments on WA CSP Rule (06.15.2011).pdf; Attachment 2- APERC Comments on CSP Rule (06.15.2011).pdf

Dear Mr. Williams,

Alkylphenols & Ethoxylates Research Council (APERC) respectfully submits the attached comment letter along with two attachments in response to the Department of Ecology's (DoE's) May 4, 2011 proposed Children's Safe Products Reporting Rule (Chapter 173-334 WAC).

Thank you for the opportunity to comment.

If you have any trouble with the attached files or questions about the content please contact me at (202) 419-1506 or blosey@regnet.com.

Respectfully,
Barbara S. Losey
Deputy Director
Alkylphenols & Ethoxylates Research Council
1250 Connecticut Ave., N.W., Suite 700
Washington, DC 20036
blosey@regnet.com
(202) 419-1506

Alkylphenols & Ethoxylates Research Council

1250 CONNECTICUT AVENUE, NW, SUITE 700, WASHINGTON, DC 20036
(202) 419-1506 WWW.APERC.ORG INFO@APERC.ORG

June 15, 2011

John Williams
Department of Ecology
PO Box 47600
Olympia, WA 98504-7600
Submitted via email: john.williams@ecy.wa.gov

Subject: Comments on Children's Safe Products Reporting Rule
(Amended version, re-filed May 4, 2011)

Dear Mr. Williams,

The Alkylphenols & Ethoxylates Research Council (APERC) respectfully submits these comments in response to the Department of Ecology's (DoE's) May 4, 2011 proposed Children's Safe Products Reporting Rule (Chapter 173-334 WAC). APERC is composed of manufacturers, processors and raw material suppliers of alkylphenols and alkylphenol ethoxylates, including nonylphenol (NP) and octylphenol (OP), which are listed as 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.

As many of the concerns that APERC previously raised regarding Ecology's October 22, 2010 proposed rule have not been addressed, either in the revised rule or in the Department's Summary and Response to Public Comment on Original Rule Proposal, we are resubmitting for the record again a copy of our January 7, 2011 comments. APERC provided extensive comments in January that included references to credible scientific studies and governmental assessments on the health effects, human exposures and risk of Nonylphenol (CAS numbers 104-40-5, 25154-52-3, and 84852-15-3) and Octylphenol (CAS numbers 1806-26-4, and 140-66-9) that support the removal of these compounds from the Reporting List of Chemicals of High Concern to Children (CHCC List) under section WAC 173-334-140. DoE's response to APERC and other comments recommending removal of NP and OP from the CHCC list was a brief statement referencing the Rationale Documents posted on the Department's website. Review of the Rationale Documents for NP and OP indicates that the justifications for the listing of these chemicals rely on a small selection of studies and do not mention the credible peer-reviewed scientific information cited in APERC's comments, which document why these chemicals fail to meet the criteria required for inclusion on the CHCC list and do not support regulation or reporting of these chemicals as CHCC in Washington State

John Williams, Washington DoE

June 15, 2011

Page 2 of 3

according to the criteria for "high priority chemicals" as defined under Washington State RCW 70.240.010(6).

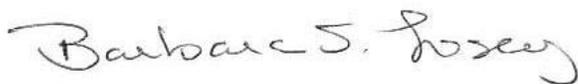
Credible authorities have determined that NP and OP are not persistent, not bioaccumulative, not mutagenic or carcinogenic, and not reproductive or developmental toxicants. NP and OP have not been shown to be toxic to the nervous or immune systems. Multi-generation rat studies that have tested for potential estrogenic effects have shown that the weak estrogenic activity of NP and OP do not 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 doses below maternal metabolic saturation and toxicity). In addition, 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 listing these compounds on the CHCC list and requiring reporting of these chemicals in products is not warranted.

APERC recommends that DoE consider the significant set of credible scientific studies and risk assessments provided in APERC's January comments, which provide a basis to remove NP and OP from the CHCC list; thereby allowing further prioritization of the CHCC list. Removing NP and OP from the CHCC list will save the business community and DoE the resources to report and review data on chemicals, which are not intentionally used in children's products and have not been shown to be a risk to humans or children. If NP and OP are not removed from the CHCC list, it is APERC's view that DoE has an obligation to respond as to why the Department is disregarding the weight of the scientific evidence for these compounds.

APERC also supports the more general comments submitted by the Association of Washington Business (AWB). In particular APERC agrees that DoE should adopt the definition of "credible scientific evidence" recommended by AWB and the American Chemistry Council. In addition, APERC supports the AWB suggestion that the CHCC list should be shortened by removing compounds such as NP and OP, which are not intentionally added to products and have not been shown, based on the weight of scientific evidence, to represent a risk to children.

Thank you for this opportunity to provide additional comment. Please contact me at (202) 419-1506 or blosey@regnet.com if you have any questions.

Respectfully,



Barbara S. Losey
Deputy Director

John Williams, Washington DoE

June 15, 2011

Page 3 of 3

Attachments:

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

Attachment 2 - Alkylphenols & Ethoxylates Research Council. (2011, January 7).
Appendix 1 to Alkylphenols & Ethoxylates Research Council Comments on
Washington State Children's Safe Product Reporting Rule, Chapter 173-334:
Evaluation of Potential Exposures and Risks Associated with Environmental
Media Concentrations of Nonylphenol and Nonylphenol Ethoxylates.

A P E R E S E A R C H C O U N C I L

1250 CONNECTICUT AVENUE, NW, SUITE 700, WASHINGTON, DC 20036
TOLL FREE: 866-APER-NA WWW.APERC.ORG INFO@APERC.ORG

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 children) 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, Xiaomeng. (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.

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 ²⁴APERC 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 do not cite human health concerns 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 Disruptors 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

²⁷Oslo 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

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

²⁹Staples, 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.

³⁰Klecka, 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-Riviere, N.A., Van Miller, J.P., Simon, G.S., Joiner, R.L., Brooks, J. and Riviere, J.E. (2003) In Vitro Percutaneous Absorption of Nonylphenol (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}

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."

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/edsoverview/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 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.

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 Canada⁷¹ and the European Union⁷² 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.

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 mg/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

<i>Reference</i>	<i>Sample collection and analysis</i>	<i>Results</i>
<p>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.</p>	<p>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.</p> <p>Analysis: GC/MS analysis using selected ion monitoring (SIM) mode</p>	<p>Nonylphenol (ng/m³; n=29) outdoor air all homes: minimum: N/A maximum: 40 median: N/A</p> <p>Nonylphenol (ng/m³; n=20) outdoor air Richmond: minimum: N/A maximum: 40 median: N/A</p> <p>Nonylphenol (ng/m³; n=9) outdoor air Bolinas: minimum: N/A maximum: 39 median: N/A</p> <p>Nonylphenol (ng/m³; n=31) indoor air all homes: minimum: N/A maximum: 89 median: 53</p> <p>Nonylphenol (ng/m³; n=21) indoor air Richmond: minimum: maximum: 89 median: 53</p> <p>Nonylphenol (ng/m³; n=10) indoor air Bolinas: minimum: 26 maximum: 89 median: 49</p> <p>Nonylphenol monoethoxylate (ng/m³; n=29) outdoor air all homes: minimum: N/A maximum: N/A median: N/A</p> <p>Nonylphenol monoethoxylate (ng/m³) outdoor air Richmond: minimum: N/A maximum: N/A median: N/A</p> <p>Nonylphenol monoethoxylate (ng/m³) outdoor air Bolinas: minimum: N/A maximum: N/A median: N/A</p> <p>Nonylphenol monoethoxylate (ng/m³; n=31) indoor air all homes: minimum: N/A maximum: 72 median: 20</p> <p>Nonylphenol monoethoxylate (ng/m³; n=21) indoor air Richmond: minimum: N/A maximum: 36 median: 19</p> <p>Nonylphenol monoethoxylate (ng/m³; n=10) indoor air Bolinas: minimum: 13 maximum: 72 median: 29</p> <p>Nonylphenol diethoxylate (ng/m³; n=29) outdoor air all homes: minimum: N/A maximum: N/A median: N/A</p> <p>Nonylphenol diethoxylate (ng/m³) outdoor air Richmond: minimum: N/A maximum: N/A median: N/A</p>

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		<p>Nonylphenol diethoxylate (ng/m³) outdoor air Bolinas: minimum: N/A maximum: N/A median: N/A</p> <p>Nonylphenol diethoxylate (ng/m³; n=31) indoor air all homes: minimum: N/A maximum: 18 median: N/A</p> <p>Nonylphenol diethoxylate (ng/m³; n=21) indoor air Richmond: minimum: N/A maximum: N/A median: N/A</p> <p>Nonylphenol diethoxylate (ng/m³; n=10) indoor air Bolinas: minimum: N/A maximum: 18 median: N/A</p>
<p>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.</p>	<p>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</p> <p>Analysis: GC/MS analysis</p>	<p>Exposures and absorbed doses were not estimated for NP, because it was quantifiable in less than 11% of the samples in any medium.</p>
<p>Costner P, Thorpe B, McPherson A. 2005. Sick of Dust. A project of Clean Production Action.</p>	<p>Sampling: Dust samples from vacuum bags in ten homes in each of seven states (CA, ME, MA, MI, NY, OR, WA)</p> <p>Analysis: GC/MS analysis using selected ion monitoring (SIM) mode</p>	<p>Nonylphenol ppm (µg/g; n=7): minimum: 3.740 maximum: 10.500 mean: 5.141</p> <p>Nonylphenol monoethoxylate ppm (µg/g; n=7): minimum: 3.720 maximum: 14.800 mean: 7.611</p> <p>Nonylphenol diethoxylate ppm (µg/g; n=7): minimum: 5.850 maximum: 17.900 mean: 9.890</p> <p>4-Octylphenol ppm (µg/g; 0/7): minimum: <RL maximum: <RL mean: <RL</p> <p>Octylphenol monoethoxylate ppm (µg/g; n=7): minimum: 0.394 maximum: 3.410 mean: 1.003</p>

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		<p>Octylphenol diethoxylate ppm ($\mu\text{g/g}$; n=7): minimum: 0.395 maximum: 8.550 mean: 1.870</p> <p>4-t-methylbutylphenol ppm ($\mu\text{g/g}$; n=7): minimum: 0.154 maximum: 0.962 mean: 0.373</p>
<p>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.</p>	<p>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</p>	<p>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 ($\mu\text{g/g}$): minimum: 4.62 maximum: 52.6 mean: 29.2 play area soil, ppm ($\mu\text{g/g}$): minimum: 0.059 maximum: 0.070 mean: 0.063</p> <p>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 ($\mu\text{g/g}$): minimum: 3.28 maximum: 9.62 mean: 7.22 play area soil, ppm ($\mu\text{g/g}$): minimum: 0.034 maximum: 0.162 mean: 0.076</p> <p>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</p> <p>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</p> <p><u>Potential daily dose</u>: 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 <u>Estimated aggregate daily dose</u> 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</p>
<p>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</p>	<p>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</p>	<p>4-nonylphenol indoor air (ng/m³; n=120): minimum: 21 maximum: 420 median: 110</p> <p>4-nonylphenol household dust ($\mu\text{g/g}$; n=118): minimum: <RL maximum: 8.68 median: 2.58</p> <p>nonylphenol monoethoxylate indoor air (ng/m³; n=120):</p>

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<p>endocrine-disrupting compounds in indoor air and dust.</p>	<p>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</p>	<p>minimum: <RL maximum: 73 median: 17</p> <p>nonylphenol monoethoxylate household dust (µg/g; n=118): minimum: <RL maximum: 15.6 median: 3.36</p> <p>nonylphenol diethoxylate indoor air (ng/m3; n=120): minimum: <RL maximum: 26 median: <RL</p> <p>nonylphenol diethoxylate household dust (µg/g; n=118): minimum: <RL maximum: 49.3 median: 5.33</p>
		<p>nonylphenol ethoxycarboxylate indoor air (ng/m3; n=30): minimum: <RL maximum: 18 median: <RL</p> <p>nonylphenol ethoxycarboxylate household dust (µg/g; n=30): minimum: <RL maximum: 9.45 median: 2.12</p> <p>octylphenol monoethoxylate indoor air (ng/m3; n=120): minimum: <RL maximum: 50 median: 8.6</p> <p>octylphenol monoethoxylate household dust (µg/g; n=118): minimum: <RL maximum: 1.99 median: 0.13</p> <p>octylphenol diethoxylate indoor air (ng/m3; n=120): minimum: <RL maximum: 120 median: <RL</p> <p>octylphenol diethoxylate household dust (µg/g; n=118): minimum: <RL maximum: 2.12 median: 0.306</p> <p>4-octylphenol indoor air (ng/m3): N/A</p> <p>4-octylphenol household dust (µg/g; n=118): minimum: <RL maximum: 0.090 Median: <RL</p>

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

Grice, Joshua (ECY)

From: Mary Mataja [mataja2004@comcast.net]
Sent: Monday, June 13, 2011 8:20 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Mary Mataja
23633 SE 221st St
Maple Valley, WA 98038

Grice, Joshua (ECY)

From: Lisa Mikesell [lisa.m.mikesell@gmail.com]
Sent: Monday, June 13, 2011 2:44 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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:

- * Companies must be require to disclose the specific products a chemical is used in, not just a broad product category like "dolls".
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- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Lisa Mikesell
7601 191st Ave E
Bonney Lake, WA 98391

Grice, Joshua (ECY)

From: Millar, Sheila A. [Millar@khlaw.com]
Sent: Wednesday, June 15, 2011 12:53 PM
To: Williams, John (ECY)
Cc: Brent Cleaveland
Subject: FJATA Comments for the Revised Children's Safe Product Act - Reporting Rule
Attachments: FJATA Comments for the Revised Children's Safe Product Act - Reporting Rule.pdf

Dear Mr. Williams,

On behalf of the Fashion Jewelry and Accessories Trade Association (FJATA), we submit the attached comments in response to the Washington State Department of Ecology's Revised Children's Safe Product Act – Reporting Rule. Should you have any questions, please do not hesitate to contact me.

Regards,

Sheila A. Millar, Partner
tel: 202.434.4143 | fax: 202.434.4646 |
millar@khlaw.com
1001 G Street, N.W., Suite 500 West |
Washington, D.C. 20001

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1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
tel. 202.434.4100
fax 202.434.4646

Writer's Direct Access
Sheila A. Millar
(202) 434-4143
millar@khlaw.com

June 15, 2011

Via Electronic Mail: john.williams@ecy.wa.gov

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

Re: Comments on the Revised 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 further comments in response to changes made to the Washington State Department of Ecology’s (“DOE”) Children's Safe Product Act – Reporting Rule (“Rule”). The Rule continues to require manufacturers of children’s jewelry 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, remains a covered “Tier 2” product under the Rule. As currently proposed, reporting obligations for companies making Tier 2 products that contain “chemicals of high concern” (“CHCC”) will take effect within 18-72 months of the Rule’s effective date, depending on the size of the manufacturer.

FJATA appreciates that DOE addressed in the revised Rule some of the concerns FJATA and others raised regarding contaminants and a *de minimis* reporting level. However, FJATA continues to believe the Rule, in its current form, will offer limited, if any, benefits given the extraordinary burdens involved, particularly since there is no *de minimis* exemption for any intentionally added substances. DOE should modify aspects of the Rule that are duplicative of other regulations, standards and requirements, and take additional steps to minimize the Rule’s burden on small businesses by taking the following actions: 1) exclude children’s jewelry from the reporting requirements because chemical hazards are being addressed through an ASTM International standard; 2) remove cadmium and phthalates from the CHCC list; 3) eliminate any required reporting for antimony in crystal as it is a necessary component of crystal; 4) adopt a complete exclusion from reporting for naturally occurring substances present in products; and 5) raise the *de minimis* reporting threshold and allow intentionally added CHCCs to take advantage of the *de minimis* reporting exemption.

KELLER AND HECKMAN LLP

John R. Williams, Jr.
June 15, 2011
Page 2

I. Products and Substances Being Addressed in Other National Venues

DOE is aware that the Rule will have a disproportionate impact on small businesses. *See* DOE, Small Business Economic Impact Statement, Publication no. 11-07-014 (April 2011), at p. 1. The vast majority of FJATA members are small businesses. To alleviate some of Rule's burdens on small businesses, DOE should exclude from the reporting requirements chemicals and substances being addressed in children's products in other venues.

A. Children's Jewelry

FJATA discussed in its previous comments that, in cooperation with the U.S. Consumer Product Safety Commission ("CPSC") and other stakeholders, it has been working to establish a voluntary children's jewelry safety standard through ASTM International. This voluntary safety standard is now in the final balloting stage and comprehensively addresses hazards, including chemical hazards, of children's jewelry. Consequently, DOE should exclude children's jewelry from the reporting requirements as it reflects a category of children's products where all hazards, including chemical hazards, are being addressed nationally.

B. Substances Currently Covered By Other Laws and Standards

FJATA believes that several substances should be eliminated from the CHCC list.

1. *Cadmium*. Cadmium should be removed from the CHCC list, or at least cadmium in children's jewelry should be excluded from required reporting. Cadmium in children's metal jewelry has been extensively evaluated by the CPSC, *see* CPSC Staff Report: Cadmium in Children's Metal Jewelry (Oct. 2010), *available at* <http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf> (hereafter "CPSC Cadmium Report"), and, as noted above, is being addressed in children's jewelry through ASTM International.

CPSC also received a petition from the Sierra Club and others seeking a total content limit on cadmium in children's jewelry. *See* CPSC Staff Briefing Package, Petition HP 10-2, Requesting Restriction of Cadmium in Toy Jewelry (Feb. 9, 2011), *available at* <http://www.cpsc.gov/library/foia/foia11/brief/cadmiumpet.pdf>. CPSC concluded, based on extensive testing, that it could not establish a total content limit for cadmium. *See* CPSC Cadmium Report at p. 55 ("soluble cadmium migration is not proportional to total cadmium content."). The CPSC tests showed non-detectable or very low detectable migratable cadmium was released from components containing cadmium at levels far higher than the threshold levels proposed for reporting by DOE (1.35% or lower). The proposed ASTM children's jewelry standard therefore establishes a conservative screening limit for certain components of children's

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jewelry (metal and plastics) and imposes migration testing in instances where total content exceeds the screening limit.

Through a unanimous vote of the Commission in February 2011, CPSC formally deferred action on cadmium in children's jewelry for six months pending finalization of the ASTM standard. *See* CPSC, Record of Commission Action, Petition HP 10-2, *available at* <http://www.cpsc.gov/library/foia/ballot/ballot11/petHP102RCA.pdf> (hereafter "CPSC Cadmium Ballot Vote"). This action is consistent with Congressional mandates that the Commission defer to voluntary standards where they address a risk of harm. Consumer Product Safety Act § 7(b)(1). As DOE would not "fill a data gap" by obtaining information about the use and presence of cadmium in children's products, and the issue is being addressed through a national standard, cadmium in children's jewelry should be excluded from burdensome reporting based on a total content standard that has been shown by CPSC's data to be unrelated to potential exposure risks to children from jewelry.

2. *Phthalates*. The revised Rule added new substances to the CHCC list, including the phthalates DEHP, DBP, BBP, DINP, DIDP, and DnOP. These phthalates are already regulated for use in children's products at the federal level through the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), and should therefore be removed from the CHCC list. DOE previously suspended enforcement for phthalate, lead and cadmium requirements under the Washington Children's Safe Products Act ("CSPA"), citing preemption by federal law. *See* Withdrawal Notice, *available at* <http://www.ecy.wa.gov/laws-rules/activity/wac173334.html>; *see also* DOE, Preliminary Cost-Benefit and Least Burdensome Alternative Analyses (April 2011), at p. 21 ("Lead in children's products is regulated by the federal [CPSIA] and substantially preempts Washington's ability to require manufacturers to report on the presence of lead."). Moreover, DOE would not "fill a data gap" by gathering information on the presence of these phthalates in children's products, much less alternatives to phthalates, as a Congressionally mandated Chronic Hazard Advisory Panel ("CHAP"), in coordination with the CPSC, is already reviewing the health effects of these substances and their possible alternatives. Accordingly, these listed phthalates are already regulated at the federal level and should be removed from the CHCC list.

3. *Antimony*. Antimony is one of the listed CHCCs. FJATA urges DOE to adopt an exclusion from reporting for antimony in crystal. Crystal is a popular material in jewelry, and antimony is an essential material used in crystal at levels around 1200 ppm. Further, it is well-known that elements like lead and antimony are closely bound in the crystal structure and will not be bioavailable to children at harmful amounts, even under extreme conditions such as accidental ingestion. There are also no alternatives to antimony when making crystal. To impose reporting obligations in such circumstances will not advance the state of knowledge of the health effects of antimony in crystal.

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II. Exemption for Trace Contaminants

While DOE has acknowledged the need to offer relief from the burdensome reporting requirements where trace contaminants are involved, the proposal does not go far enough to mitigate the burdens of unnecessary reporting in general and appears inconsistent with the statutory intent. 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). We believe that the intent of this provision is that trace contaminants, whether naturally occurring or otherwise, should be entirely excluded from reporting, since they do not serve a function that is reportable.

Further, the revised rule does not provide for an adequate exemption for reporting in situations where a listed substance is naturally occurring. It is entirely possible that in a complex product the total content of a listed CHCC could exceed 100 ppm. This has been shown to be the case with lead in metal alloys and plated metals, for example. We suggest amending the definition of a “contaminant” in proposed section WAC 173-334-040 as follows:

They can include, but are not limited to, naturally occurring substances, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products.

As currently drafted, the Rule would provide an exemption for contaminants present in an amount under 100 ppm from the reporting requirement. However, if a trace contaminant is present at levels above 100 ppm, to avoid reporting the manufacturer must have in place a control program that meets the requirements of WAC 173-334-120(2). It is not clear what type of program a manufacturer could put in place to control naturally occurring substances. Naturally occurring substances should be categorically excluded from reporting since, by their nature, they do not have a technical function in the product and cannot be eliminated through the exercise of due diligence.

To the extent DOE retains the control program requirement to support an appropriate *de minimis* exemption for reporting the presence of manufacturing contaminants in children’s products, the Rule should be clarified to ensure that the importer of children’s products who does not otherwise manufacture the products it imports can utilize the exclusion. This clarification could provide that the importer must be aware that a control program was in place at the manufacturing stage. Rules should also clearly establish that chemical and/or material self-declarations are an acceptable alternative to product testing to support exemptions. As drafted, this provision suggests that affected children’s jewelry manufacturers may have to test all product components for all listed substances, even if just to prove the absence of a listed substance from components so as not to be found lacking in due diligence in the control

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program. At the 100 ppm *de minimis* level proposed, this will likely expand testing obligations and costs exponentially. Again, FJATA believes the 100 ppm *de minimis* threshold proposed is too low.

III. *De Minimis* Reporting Thresholds

As noted above, the proposed 100 ppm threshold for trace contaminants does not take into account that naturally occurring trace contaminants could exceed this limit. It also fails to acknowledge the extensive burdens imposed by reporting small amounts of intentionally added substances. The benefits to be gained cannot possibly justify the costs of the reporting. FJATA continues to believe that a default 0.1% *de minimis* level should be adopted for all substances on the reporting list, regardless of whether they were intentionally introduced into the product. This will make reporting obligations more manageable as the program is phased in and can be revised by DOE through a chemical specific, scientific process based on a more explicit understanding of how chemicals or other substances are used.

DOE's initial thinking on an appropriate *de minimis* level in its Phase 3 Report was to adopt a 0.1% level. In fact, a 0.1% threshold reflects the European Union's REACH legislation and Section 313 of the Superfund Amendments and Reauthorization Act. These programs are intended to gather information on the use of chemicals, operating similarly to the reporting Rule. No justification or explanation for why the Department moved away from this earlier policy has been made available. Thus, not only would formal adoption of a general 0.1% *de minimis* threshold simplify the reporting process and potentially minimize the burden on small businesses, it would reflect a level determined by numerous regulatory bodies to be an appropriate trigger for an information reporting scheme.

Requiring manufacturers to report on the presence of CHCCs in amounts as low as 100 ppm, whether added intentionally or not, will not translate to a better understanding of a product's safety. DOE previously acknowledged that "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; *see also* WAC 173-334-010 ("The presence of a CHCC in a children's product does not necessarily mean that the product is harmful to human health"). Exposure, not presence, is key to understanding risks. CPSC data on exposure to cadmium in children's products has confirmed this point. *See* CPSC Cadmium Report at p. 55.

FJATA therefore continues to suggest that at this stage a 0.1% *de minimis* threshold be used. These exemption thresholds can be modified going forward based on scientific evidence supporting a lower threshold on a case by case basis. This will substantially reduce the burden imposed by this Rule on manufacturers who safely use CHCCs for which no alternatives exist, in

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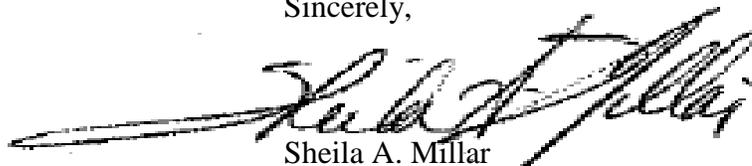
what are routinely considered *de minimis* quantities under other regulatory schemes, or in accordance with other laws, regulations or safety standards.

IV. Conclusion

FJATA urges DOE to reduce the burdens imposed by this Rule as it currently includes duplicative obligations on children's fashion jewelry manufacturers who are already regulated at the federal level. 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 for this substance in jewelry. The CPSC's technical research rejects the proposition that a total content limit for cadmium is technically sound, and that input is being incorporated into a third-party consensus safety standard that addresses cadmium in children's jewelry. A federal mandatory standard applies to phthalates in specified children's products; Congress deliberately determined which subset of children's products should be covered, so DOE should remove phthalates from the CHCC list as a result. Moreover, a federally-commissioned CHAP is reviewing phthalate alternatives. FJATA also urges that the CHCC list exclude antimony in crystal. DOE should also categorically exclude naturally occurring substances from the reporting obligations, regardless of whether a control program is in place, and establish appropriate *de minimis* reporting threshold of 0.1% 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

Grice, Joshua (ECY)

From: Tom Myers [myerst@personalcarecouncil.org]
Sent: Tuesday, June 14, 2011 12:58 PM
To: Williams, John (ECY)
Cc: Williams, John (ECY)
Subject: Comments on WA DOE's Revised Proposed Reporting Rule - Rule Proposal notice Ch 173-334 WAC
Attachments: Comments to WA REVISED Proposed Reporting Rule 061511 (scanned).PDF

John –

Attached are the Personal Care Products Council's comments to the "revised" proposed rule, which is intended to implement the reporting requirements of the Children's Safe product Act of 2008.

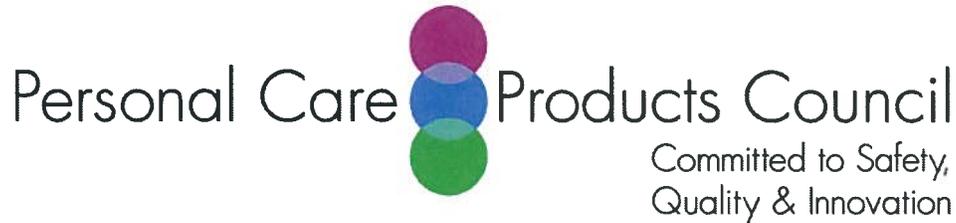
Thank you and please let me know if you have any questions.

Best,

Tom

THOMAS F. MYERS
Associate General Counsel
T: 202.331.1770
F: 202.331.1969

Personal Care Products Council
1101 17th Street, NW STE 300
Washington, DC 20036-4702
www.PersonalCareCouncil.org



June 14, 2011

John R. Williams
Washington State Department of Ecology
W2R HQ
PO Box 47775
Olympia, WA 98540-7775
john.williams@ecy.wa.gov

Re: Comments on the “Revised” Proposed 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.

The Council applauds many of the changes that DOE made to the draft rule following the last round of comments, and particularly those clarifications to the definition of children’s product and the term intentionally-added. Nevertheless, the Council still has a number of concerns with the proposed rule, including the following key points:

- 1. Emerging science, such as endocrine disruption, should be evaluated using a scientifically valid “weight of evidence” approach. Hazard classifications based solely on endocrine disruption should be removed from the proposed rule.**

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).

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2. **Reporting tiers should be revised based on actual or realistic use scenarios and the potential exposure to exposure route(s) of concern.**
3. **Remove or revise the reporting extension for ingredients under alternative assessment evaluation, and eliminate the terms “safer” or “alternative assessment” until the definition and methods are established.**
4. **Provide in the definition of “reporting” that authoritative conclusions/summaries are sufficient to meet the reporting requirement as defined by Children’s Safe Products law.**
5. **Provide in the definition of “presence” that international standards or levels established by authoritative bodies may be used to identify the presence of a contaminant in a finished product.**

Endocrine Disruption

Although not considered a toxic endpoint, endocrine activity is often used as evidence for potential adverse impact. Unlike the hazard assessment for carcinogenicity or reproductive toxicity, however, the science on endocrine disruption is still developing. DOE includes endocrine disruption in this proposed rule based on its classification in an European Union (EU) commission study. Many of the ingredients identified by the EU commission study show endocrine activity at levels much lower than natural human hormones. Importantly, the objective of the EU study was explicitly to identify candidates for further research. Whether these are true endocrine disruptors requires a more detailed investigation. The EU commission even cautioned that there is not a broadly accepted definition of endocrine disruption.

It is critical that a scientifically valid “weight of evidence” approach be utilized when addressing emerging science issues such as endocrine disruption. It is unclear that such an approach was applied in developing the Chemicals of High Concern for Children (CHCC) list, as the evidence presented is only a list of publications, without dissenting opinions.

Consider, for example, parabens. 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.³ However, evidence that these findings have any significance *in vivo* is mixed at best. There is no consistent evidence that exposure to

³ Witorsch R and Thomas J. Personal care products and endocrine disruption: a critical review of the literature. *Crit Rev Toxicol* 2010, 40: 1-30.

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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” (GRAS) list as Category 1 substances. 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 yet DOE can simultaneously classify them as a CHCC.

Similarly, the Cosmetic Ingredient Review (CIR)⁴ 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.

Currently, butyl, ethyl, methyl and propyl paraben are listed by DOE as CHCCs. The Council believes these listings, as well as those chemicals classified as hazardous based solely on endocrine disruption, are in error based on the medical literature available and the failure to utilize a “weight of evidence” approach. Consequently, the Council recommends that all such chemicals be removed from the CHCC list.

Product Tiers/Exposure

Another concern that the Council has with the proposed rule relates to the “product tiers” contained in the manufacturer notice provision. It appears that the product tiers are inconsistently applied, and do not properly reflect actual exposure and routes of exposure. Tier 1, for example, includes ingested products with skin care products. But the bioavailability of oral vs. dermal routes differs significantly. While it is true that some cosmetic products for small children do have a potential for incidental ingestion, most “Leave On” cosmetic lotions are more aligned with Tier 2, described as skin contact for more than one hour. “Wash Off” products including shampoos have even less exposure. A related concern is the absence of other exposure routes beyond dermal and oral. Some ingredients on the DOE

⁴ 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.

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list are classified as inhalation hazards. Without reference to the exposure route of concern, some products could be incorrectly over or under prioritized.

Based on the foregoing, the Council recommends modifying the product tiers to better reflect reasonable use and potential exposure routes of concern.

Undefined References

Undefined references to “safer” products or “alternative assessments” conflict with the primary objective of the reporting rule to confirm product and exposure assumptions. The proposed rule, for example, states that chemicals included in the CHCC list are not necessarily harmful, yet then provides an extension for companies that are conducting a “safer alternative assessment”. Any preliminary alternative assessment or commercial reformulation activity can be misleading, implying that the ingredient or contaminant level is already unsafe. As such, the Council recommends that DOE remove or revise the reporting extension for ingredients under the alternative assessment evaluation, and eliminate the terms “safer” or “alternative assessment” until the definition and methods are established

Information in the public domain

CHCC (Chemicals of High Concern for Children List) includes ingredients that have been evaluated by many authorities and determined to be safe for cosmetic use, including cosmetics for children. As noted above, parabens have been evaluated and determined safe by recognized authoritative bodies, including CIR. Their maximum allowed use levels and restrictions are publicly available, and as ingredients they appear on the product label. It remains unclear, however, whether companies need to report information to DOE that is already publicly available. The Council recommends that DOE define the term “reporting” to state that the conclusions of recognized authoritative bodies are sufficient to meet the law’s reporting requirement.

Reporting Trigger Level

The proposal to impose a new and unique reporting requirement based on a range of levels for all intentionally added chemicals above a “PQL” places an unsubstantiated, transient, and highly burdensome requirement on product manufacturers and distributors without providing a concurrent consumer or public benefit. Modern analytical methodology is extraordinarily sensitive with limits of detection even in the parts per trillion (ppt) range. The resources necessary to evaluate and products for components at this level can be significant and substantial. Further, the public benefit for measuring and reporting such extremely low levels for any listed chemical appears arbitrary.

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Rather than imposing a new and unique reporting requirement based on a range of levels for all intentionally and unintentionally listed chemicals, we strongly recommend DOE establish a reporting requirement consistent with the 0.1% *de minimis* threshold that is currently the standard in other national and international laws such as the global communication standards, established by the Globally Harmonized System and EU's Classification, Labeling and Packaging regulation. Reporting requirements below the threshold level below 0.1% threshold should be reserved for those chemicals that are recognized as being carcinogenic, mutagenic and reproductive toxicity, (CMR) by authoritative bodies biologically relevant for direct [human] exposure.

Global harmonized trigger levels have been established under these systems based on the potential hazard of the ingredient or contaminant. Using reporting triggers different than those used internationally will result in unnecessary delays and expended resources. Comparison across companies and industries is questionable as the source of the data will vary from information collected through the supply chain to analytical testing, using different methods. The quality and confidence levels will be significantly impacted by using arbitrarily selected lower levels that differ from international standards.

Conclusion

The Council would like to thank DOE for the opportunity to provide comments on the revised 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

Grice, Joshua (ECY)

From: Grant Nelson [GrantN@AWB.ORG]
Sent: Wednesday, June 15, 2011 4:48 PM
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 CSPA Reporting Rule - AWB Comments
Attachments: Ecology CSPA Reporting Rule - AWB Comments 6-15-11.pdf

Dear Mr. Williams,

Please find attached AWB's comments regarding Ecology's proposed Children's Safe Products Action Reporting Rule.

We appreciate the department's consideration of these comments prior to adopting the final rule.

Thank you.

GRANT A. NELSON
ASSOCIATION OF WASHINGTON BUSINESS
Government Affairs Director

T 360.943.1600 / T 800.521.9325
M 360.870.2917 / F 360.943.5811
PO Box 658, Olympia, WA 98507-0658
www.awb.org



June 15, 2011

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

submitted via email: john.williams@ecy.wa.gov

**Subject: AWB Comments – Children’s Safe Products Reporting Rule
 (Amended version, re-filed May 4, 2011)**

Dear Mr. Williams,

The Association of Washington Business (AWB) submits the following comments regarding the Department of Ecology’s May 4, 2011 proposed Children’s Safe Products Reporting Rule (Chapter 173-334 WAC). As many of the concerns that AWB previously raised regarding Ecology’s previously proposed rule have not yet been addressed by the department, we are resubmitting for the record again a copy of our January 7, 2011 comments.

Although the proposed rule will create unnecessary burdens on manufacturers, especially small businesses, AWB commends the department for making a number of improvements in this latest proposed draft, including:

- 1) Raising the reporting threshold from 40 parts per million (ppm) to 100 ppm for chemicals that are not intentionally added. This is a move in the right direction, but not nearly far enough as highlighted below in more detail;
- 2) Exempting manufacturers from reporting chemical contaminants when a manufacturing control system is in place. Again, a move in the right direction, but AWB believes that the reporting rule should be limited to intentionally added ingredients;

ASSOCIATION OF WASHINGTON BUSINESS
Membership Government Affairs Member Services AWB Institute

T 360.943.1600 ✉ PO Box 658, Olympia, WA 98507-0658
T 800.521.9325 🏠 1414 Cherry St. SE, Olympia
F 360.943.5811 www.awb.org

- 3) Clarifying that the presence of chemicals of high concern to children (CHCC) in a product does not equate to a danger to human health or a violation of existing safety standards. This is an important fact that needs to be clearly communicated in all department communications;
- 4) Adding definitions of “children’s product”, “contaminant”, “intentionally added” and other definitions to clarify the scope of the rule.

While the above changes incorporated into the proposed rule are appreciated, the department needs to re-examine the intent of RCW 70.240 and ensure that the final rule meets the requirements of adopting the least burdensome alternative, required in RCW 34.05.328, which states,

*“(e) Determine, after considering alternative versions of the rule and the analysis required under (b), (c), and (d) of this subsection, that the rule being adopted is **the least burdensome alternative for those required to comply** with it that will achieve the general goals and specific objectives stated under (a) of this subsection;”*

AWB members believe that Ecology’s proposed CSPA reporting rule fails to meet the requirement of RCW 35.05.328(e) in a number of critically important ways, including:

- 1) WAC 173-334-080(a). The lowest level threshold for reporting of intentionally added chemicals is the practical quantification limit (PQL). This threshold is far too low, and will create an unnecessary burden on manufacturers. AWB requests that the lowest threshold begin at 1,000 ppm. 1,000 ppm has been recognized by the European Union as the lowest threshold necessary to provide sufficient information regarding consumer products, whilst not creating an unnecessary burden on businesses. Especially given the current economic recession, citizens and businesses would be well served by a threshold of 1,000 ppm, while a lower threshold will serve little use, except to drive up costs of reporting for manufacturers.
- 2) WAC 173-334-080(b). While AWB members do appreciate the exemption for reporting of contaminant chemicals when a manufacturing control system is in place, we believe that reporting of contaminants should be eliminated from the rule. As we articulated in our earlier comments, Washington should be consistent with other states and countries that only require intentionally added ingredients to be reported, not contaminants. Limiting reporting to intentionally added ingredients is

also consistent with the July 2010 Department of Health & University of Washington report submitted to Ecology.

- 3) WAC 173-334-080(7). A new subsection (7) is needed to exempt inaccessible parts. AWB requests that 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. Alternatively, an exemption for inaccessible parts could be provided in WAC 173-334-040(b).

Additional comments and concerns:

- 1) Potential decreased consumer confidence and spending. As mentioned above, AWB appreciates the department clarifying in WAC 173-334-101 that the presence of a CHCC does not equate to a danger for human health. AWB requests that the department continue to educate citizens in Washington state of this fact in all agency communications. It is critically important that Ecology not create a panic among consumers that leads to decreased consumer confidence and spending, which would harm Washington businesses and worsen our already fragile economy.
- 2) Confidential Business Information (CBI). Manufacturers of products must have the ability to keep competitors from gaining knowledge of key ingredients and processes used in the manufacturing of their products. Our members are concerned that the reporting requirements of the proposed rule could jeopardize confidential business information.
- 3) Credible peer-reviewed scientific information. The proposed rule references “credible peer-reviewed scientific information” in WAC 173-334-070(4)(c) but provides no definition of this term. AWB supports comments submitted by the American Chemistry Council, outlining a systematic approach (“Klimisch codes”) for evaluating the quality and reliability of scientific studies. AWB supports the use of this methodology by the department when deciding whether to add or remove a chemical from the CHCC list.
- 4) The list of CHCCs is too way long. Many chemicals should be removed from the CHCC list that manufacturers are required to report. As AWB articulated in our January 7, 2011 comments, the Department of Health and the University of

Washington reported that 27 chemicals on Ecology's list are not intentionally added. Those chemicals should be removed from the list. AWB especially believes that Ecology has not made a compelling case why phthalates, parabens and nonylphenols have been added to the list of CHCC and requests that these chemicals be removed.

- 5) Disclosure of evidence lacking. AWB and member organizations are concerned that the department is not required to disclose the evidence it relied upon in placing a chemical on the CHCC. Parabens, for example have been included on the CHCC list. Given that the Food and Drug Administration (FDA) has stated that there is no evidence in available information that demonstrates or suggests reasonable grounds to suspect that these parabens present a hazard when they are used at current levels, and that the FDA already subjects parabens-containing products to rigorous regulation, their inclusion on the list at this time is contrary to accepted scientific standards. Parabens should therefore be removed from the list or Ecology should disclose the evidence it relied upon for their inclusion.

AWB appreciates the department's consideration of these comments prior to moving forward with adopting a final CSPA reporting rule. We encourage Ecology to adopt a rule that is practical, does not place unnecessary burdens on manufacturers of children's products and complies with RCW 43.05.328 regarding significant legislative rules.

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

Grice, Joshua (ECY)

From: Thom Peters [onthehouse@aol.com]
Sent: Monday, June 13, 2011 6:00 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Thom Peters
7725 Riverview Road
Snohomish, WA 98290-5884

Grice, Joshua (ECY)

From: Kristin Power [KPower@cspa.org]
Sent: Wednesday, June 15, 2011 1:45 PM
To: Williams, John (ECY)
Subject: Revised Rule Proposal Notice Chapter 173-334 WAC - Children's Safe Products Reporting Rule
Attachments: WA Children's Safe Products Reporting Rule CSPA Comments 6.15.11.pdf

Mr. Williams,

Thank you for the opportunity to comment on the revised proposed Children's Safe Products Reporting Rule. CSPA's comments on the rule are attached. Please contact me at (916) 838-3587 or kpower@cspa.org if you have questions regarding the comments.

Kristin Power

Kristin Power
Director, State Affairs – West Region

900 17th Street Suite 300
Washington, DC 20006

kpower@cspa.org
P (202) 833-7314
F (202) 872-0720

www.cspa.org



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Representing Household & Institutional Products

Aerosol - Air Care - Cleaners - Polishes
Automotive Care - Antimicrobial - Pest Management

June 15, 2011

Via E-Mail: johnwilliams@ecy.wa.gov

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

**Re: Revised 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 revised Children’s Safe Products Reporting Rule (Rule Proposal Notice Chapter 173-334 WAC).

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/>.

¹ The Consumer Specialty Products Association (CSPA) is the premier trade association representing the interests of approximately 240 companies engaged in the manufacture, formulation, distribution and sale of approximately \$80 billion annually in the U.S. of hundreds of familiar consumer products that help household and institutional customers create cleaner and healthier environments. Our products include disinfectants that kill germs in homes, hospitals and restaurants; candles, and fragrances and air fresheners that eliminate odors; pest management products for home, garden and pets; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day. Through its product stewardship program, Product Care®, and scientific and business-to-business endeavors, CSPA provides its members a platform to effectively address issues regarding the health, safety, sustainability and environmental impacts of their products. For more information, please visit www.cspa.org.

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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 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.

We appreciate the thoughtful review of comments received in the initial public comment period and request reconsideration of some of the issues we raised in that comment period. We also have concerns with some of the new language in the revised proposed rule. Green chemistry should ensure the safety of consumer products through the use of risk-based sound science in the decision-making process. We believe a green chemistry program should build on existing statutory and regulatory structures, voluntary initiatives, and data development efforts. Further, we believe a green chemistry program should ensure that product efficacy, performance, and usability are not compromised or undermined. In that spirit, the following comments are offered on the revised Children's Safe Products – Reporting Rule.

WAC 173-334-080

The sophistication of today's analytical methods makes it possible to detect chemicals well into the parts-per-billion and even parts-per-trillion levels. In addition these extremely low levels do not inherently present a safety concern for any child that uses or comes into contact with the finished product. Lowering the reporting trigger for intentionally-added chemicals to the "practical quantization limit" is at odds with other international and US regulatory agencies' recognition of threshold level. An unreasonably low reporting trigger also adds considerable cost and wasted effort to the final product that is passed onto the consumer without any improved safety benefit to a child. A workable *de minimis* is needed for intentionally-added

Mr. John Williams, Jr.

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chemicals and should be set at 0.1% to remain consistent with international and other US regulatory agencies' recognition of threshold level.

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 handling and use should not be sufficient to list that chemical when it itself does not meet the toxicity, persistence, bioaccumulativity or exposure criteria.

CSPA appreciates the Department of Ecology acknowledging a 0.01% *de minimis* by raising the reporting trigger for contaminants from 40 ppm to 100 pm, however, we respectfully request that the scope of the Children's Safe Products rule should focus on intentionally-added chemicals in children's products.

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 European Union GHS establishes chemical-specific thresholds that may be lower or higher than 0.1% based on sound science and reliable information. We think it is more appropriate to adopt a regulatory approach that is consistent with international protocols which allow manufacturers to more accurately report levels which have been subject to thorough testing and do not overestimate the actual material present. To do otherwise would cause unnecessary consumer concern and may mean actual levels are taken out of context.

Therefore, we request amendments to delete (e) (i), (ii) and (iii) for all listed chemicals, resulting in a default reporting *de minimis* of 1000 ppm (0.1%). This section should be further amended to allow the Department to establish a lower or higher reporting requirement for certain listed chemicals if scientifically warranted.

WAC 173-334-110

CSPA again 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.

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This 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.

The Department of Ecology makes two arguments as to why total sales should be used. First, 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." However, companies will have to make a determination of exactly which of their products are subject to the law, in light of the CSPA's definitions and exemptions, in order to undertake the assessment of the products' composition against the Chemicals of High Concern to Children list. From that definitive list of products that are in scope, a company should have sales figures available. If there are companies that cannot undertake such a sales analysis, the rule could give them the option of reporting by total sales.

If the Department of Ecology's use of sales data is truly to be a "proxy for the number of products children will potentially come into contact with", use of total company sales will vastly overstate the number of products.

Second, per the Department of Ecology's response, "some manufacturers indicate that this type of detailed information should be considered CBI." Again, to address this concern, the rule could give the option of reporting by total sales, for those companies which feel the large range of sales data for their children's products is confidential business information.

Scope of Products Covered by the Rule

CSPA has concerns about the scope of the "children's cosmetics" definition. As defined by the Act, "children's cosmetics" are those cosmetics that are made for, marketed for use by, or marketed to children under the age of 12. We support this definition to the extent that it recognizes that a manufacturer's primary intent should be the determining factor. A manufacturer's intent based upon product type, labeling, promotion and advertising should be the primary determinant regarding what is a children's product. 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

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(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.

Shelving decisions are at the discretion of retailers and manufacturers do not decide where their products are sold. For example, if a major chain store in Washington 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 rule? To what extent are manufacturers obligated to monitor and track what retailers choose to do with brand names in their stores? We suggest that manufacturer's intent based on labeling, advertising and promotion is a more meaningful and logical standard.

WAC 173-334-130

The inclusion of DEP on the Chemicals of High Concern to Children list is unprecedented and the rationale provided is insufficient.² With respect to criteria b) (Cause cancer, genetic damage or reproductive harm), the following issues are raised. In a study published by Api and summarized by reference 2³, diethyl phthalate was evaluated in a two-generation reproductive toxicity study in CD-1 mice. F0 mice were fed diets containing 0.0%, 0.25%, 1.25%, or 2.5% (~3,250 mg/kg/day) during pre-mating, mating, gestation and lactation; the F1 generation received 0.0% or 2.5%. No adverse effects on the physiology, fertility or reproductive performance were observed in the F0 generation. The F1 generation males showed decreased sperm concentration, however no adverse effects were observed on fertility. The F1 generation showed significantly lower live pups per litter at the high dose; however there was no dose response for this effect as the lowest dose showed statistically higher numbers of live births in the F0 generation (0.25%). Based on a lack of dose response for this effect and the high dose evaluated, the relevance of this result is questionable. In addition, in the original publication the authors conclude there was a lack of reproductive effects by DEP. In contrast, the weight of evidence for reproductive and developmental effects of other phthalates (DEHP for example) is clearer.⁴

With respect to criteria c) (Disrupt the endocrine system), the following issues are raised. Diethyl phthalate is currently unclassified by the European Union for reproductive or

² <http://www.ecy.wa.gov/programs/swfa/cspa/pdf/84662.pdf>

³ Api, A. M. "Toxicological profile of diethyl phthalate: a vehicle for fragrance and cosmetic ingredients", Food and Chemical Toxicology, 39, (2001) 97-108.

⁴ ATSDR (2002). Toxicological Profile for Di(2-ethylhexyl)phthalate
<http://www.atsdr.cdc.gov/ToxProfiles/tp9.pdf> .

Mr. John Williams, Jr.

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developmental toxicity. In a study commissioned by the European Union (Reference 1), the data for 435 chemicals was evaluated and the chemicals prioritized for further research by the European Union. In that study, diethyl phthalate was identified as a category 1 chemical, or a chemical for which further research is necessary. The definition of a category 1 chemical was that there was at least one study providing evidence of endocrine disruption in an intact organism. This was not a weight of evidence approach, nor is it clear if such reductions on sperm count would translate to any adverse functional outcome. Therefore, as no rationale is provided for Chemicals of High Concern to Children listing criteria a, d, e & f and there is insufficient evidence for the other two, we request DEP is not included on the list.

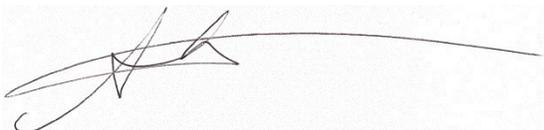
In addition, the federal Consumer Product Safety Improvement Act of 2008 treats phthalates differently: Three phthalates are banned in toys and childcare articles for children under the age of 12 (DBP, BBP and DEHP) and three (DINP, DIDP, and DnOP) are prohibited in toys and childcare articles that can be mouthed, for children three years and under pending a review by the Chronic Hazard Advisory Panel (CHAP). The CHAP will make a recommendation to the Consumer Product Safety Commission (CPSC) on whether the temporary prohibition should be continued (and if other alternative plasticizers need to be restricted). We request Department of Environment defer action to include the three interim prohibited phthalates until CPSC has completed their review and promulgated the final rule.

Summary and Conclusions

CSPA appreciates the opportunity to comment on the revised Children's Safe Products Reporting Rule and the stakeholder outreach and communication. We 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,



Steven Bennett
Director,
Scientific 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

Grice, Joshua (ECY)

From: Walter Reiter [wreiter@epscentral.org]
Sent: Thursday, June 02, 2011 12:13 PM
To: Williams, John (ECY)
Subject: Comment to proposed rule CSPA
Attachments: wash CSPA cor june 2011.pdf

Walter Reiter | Deputy Director
EPS Molders Association
1298 Cronson Blvd, Suite 201 | Crofton, MD 21114
Phone: 410.451.8341 | Fax: 410.451.8343
wreiter@epscentral.org | www.epsmolders.org



12980 Crofton Rd, Suite 201
Crofton, MD 21114
(800) 607-3772
www.epsmolders.org

June 2, 2011

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

Submitted via email: john.williams@ecy.wa.gov

RE: Comments on Listing of HBCD as a Chemical of High Concern under Children's Safe Product Act

Dear Mr. Williams,

The EPS Molders Association (EPSMA) requests that the Washington Department of Ecology (WDE) consider removing hexabromocyclododecane (HBCD) from the chemicals of high concern list and defer action under the Washington Children's Safe Product Act to permit the alternative assessment currently underway by the Environmental Protection Agency to conclude. In its present use there is not a direct exposure pathway to the class sought to be protected by the Act, the EPA is actively assessing safer alternatives, and HBCD has been found to not present a danger to human health or life.

EPS foam, in addition to its wide use as energy-saving insulation in high-performance buildings, is also used in safety equipment such as helmets and pads which might qualify as Children's Products under the Act. Flame retardants such as HBCD are not required in helmets or packaging materials. However, all insulation used in building and construction must meet flame resistance standards which often requires the addition of a flame retardant. HBCD is the most efficient, stable and effective flame retardant additive available for EPS foam insulation.

As set out below, listing HBCD will do little to protect the health of the intended protected class and cause de-selection of a safe, efficient high-performance product that delivers the benefit of more energy efficient buildings and effective protective equipment.

STUDIES DO NOT SUPPORT PRIORITY DESIGNATION

A review of available studies does not support the conclusion that HBCD warrants designation as a chemical of high concern. The state of the science and determinations reached by the European Commission and Health Canada do not support such an aggressive approach towards HBCD in its present uses.

WDE cited the European Commission's report as mentioned above as a justification for its concern over HBCD's effect on human health, yet it overlooks the Commission's conclusion that HBCD is not considered a human health toxin. In addition to the European Commission, The [Draft Screening Assessment Report by Health Canada](#) released August 28, 2010 concluded that HBCD is unlikely to result in direct adverse effects to soil organisms and wildlife and that HBCD is not entering the environment in

a quantity or concentration or under conditions that constitute or may constitute a danger to human life or health.

Furthermore, in the study by Makoto Ema, *et al.*ⁱ, cited in the EPA's HBCD Action Plan, references to this report have failed to note that the authors' "findings suggest that HBCD has no effects on androgenic/estrogenic events or sexual differentiation." (at page 347). The essence of that study is presented quite clearly by the authors as follows:

"In conclusion, the results of the two-generation reproductive toxicity study described here provide a more comprehensive toxicity profile of HBCD than has previously been reported, and that the NOAEL [no observable adverse effects level] of HBCD in this study was considered to be 150 ppm in rats. . . . The estimated human intake of HBCD is well below the NOAEL in the present study." (at page 350)

EPSMA requests that the Washington Department of Ecology re-evaluate the actual scientific studies relied upon and review the conclusions reached by both the European Commission and Health Canada. Although HBCD has been found in many locations and in many organisms, the science indicates that HBCD does not present a significant threat to the environment or humans.

HBCD IN EPS FOAM INSULATION DOES NOT PRESENT AN EXPOSURE HAZARD TO OCCUPANTS

HBCD is the flame retardant of choice for EPS rigid foam insulation because it is effective in very low concentrations and remains stable in the polymer matrix. HBCD is typically present in concentration of .6% by volume, far lower than concentrations formerly found in textiles, upholstery and apparel. Furthermore, insulation products are contained and sealed within building structures and are not exposed to the environment or occupants throughout their useful life.

Although it does not appear that any of these products would be classified as a Children's Product the listing of the compound will likely raise concerns and cause unwarranted de-selection based on misconceptions and unintended conclusions. The stated purpose of the Act is to protect children. The de-selection of rigid foam insulation, a reasonably likely unintended consequence, is well beyond the stated scope of the Act. Children or occupants are not be exposed to HBCD as it remains within the polymer matrix of EPS foam insulation typically encapsulated behind plywood, drywall, housewrap and siding.

Since there is no prevalent exposure pathway between HBCD in EPS foam insulation and infants, children or the general public, EPSMA requests that the WDE reconsider its listing of HBCD as a chemical of concern.

INDUSTRY IS WORKING TOWARDS SAFER FLAME RETARDANTS

Industry has recently announced the development of a safer flame retardant alternative for EPS foam insulation. Many hurdles remain before this or any new material could replace HBCD. In addition to creating an effective flame retardant, scientists and industry must perfect the formulation and its incorporation into EPS rigid foam insulation. Once the product is commercialized, it must undergo rigorous performance and safety testing.

EPS rigid foam insulation is a sophisticated, high performance building material. There are other insulating materials, but none that offer the unique structural and compressive strength and thermal resistance of EPS foam. A review of any high performance building project, such as a net zero structure or any passive house, will reveal generous use of rigid foam insulation.

The EPA Design for Environment program has set a timeline for study and assessment of alternatives for HBCD with a deadline of January 2012 for release of its findings. Minnesota should allow the EPA to complete the DfE study and the assessment of HBCD and the potential alternatives. EPSMA requests that in light of the Federal activity regarding the safer alternative flame retardant for EPA foam insulation that the MDH allow the EPA to continue to address HBCD in rigid foam insulation.

For these reasons and in light of the U.S. EPA's current DfE study, we would urge WDE to revisit its conclusions about HBCD and reconsider its listing as a chemical of concern.

The EPS Molders Association (EPSMA) is a trade association representing the North American expanded polystyrene (EPS) foam industry. Our members operate facilities throughout the United States including Washington. We would welcome the opportunity to assist MDH with any further questions as it seeks to more fully understand the risks associated with HBCD and its use in EPS foam. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'W. Reiter', with a stylized flourish at the end.

Walter Reiter
Deputy Director
EPS MOLDERS ASSOCIATION

¹ Ema, M., Fujii, S., Hirata-Koizumi, M., and Matsumoto, K. 2008. Two-generation reproductive toxicity study of the flame retardant hexabromcyclododecane in rats. *Reproductive Toxicology*, 25:335-351.

Grice, Joshua (ECY)

From: Reingard Rieger [gard_rein@hotmail.com]
Sent: Monday, June 13, 2011 9:44 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Reingard Rieger
8804 Ashworth Ave N
Seattle, WA 98103

Grice, Joshua (ECY)

From: Risotto, Steve [Steve_Risotto@americanchemistry.com]
Sent: Wednesday, June 15, 2011 4:02 PM
To: Williams, John (ECY)
Subject: ACC Phthalates comment on the CPSA reporting proposal
Attachments: ACC PEP comments on 173-334 WAC.pdf

John –

The ACC PE Panel’s comments on the proposal are attached.

Steve

Steve Risotto
steve_risotto@americanchemistry.com
(202) 249-6727 (o)
(571) 255-0381 (m)

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June 15, 2011

BY ELECTRONIC MAIL

Mr. John R. Williams
Washington State Department of Ecology
PO Box 4760
Olympia, WA 98504-7600

Re: Children's Safe Product Act, Reporting Rule (Chapter 173-334 WAC)

Dear Mr. Williams:

The Phthalate Esters Panel (PE Panel) of the American Chemistry Council appreciates the opportunity to provide comments on the Department of Ecology's (DOE) proposed reporting rule to implement the reporting requirements of the Children's Safe Product Act (CSPA). The list of chemicals of high concern to children (CHCC) included in the proposal includes eight phthalates and a metabolite and important precursor in phthalate manufacture (phthalic anhydride). The proposal also would establish a reporting threshold of 100 parts per million (ppm) or lower for all substances subject to the rule. The Panel represents the North American manufacturers of several of the phthalates included in the proposal that could be substantially impacted by the Department's proposed CSPA reporting requirements. As set forth below, the Panel urges DOE to remove these substances from the draft reporting list and to eliminate the reporting thresholds or to replace them with *de minimis* limits already in use in the US and Europe.

The CPSIA Phthalates Should Not Be Subject to Reporting

Among the phthalates that would be subject to the Department's proposed reporting requirement are the three phthalates subject to a permanent prohibition from toys and child care articles by the federal Consumer Product Safety Improvement Act (CPSIA) of 2008 – DBP, BBP, DEHP¹ – and the three substances subject to an interim prohibition from child care articles and toys that can be mouthed under the CPSIA - DINP, DIDP, and DnOP. Based on the federal requirement, the Department had previously determined not to include these six phthalates on the list of substances subject to reporting. DOE had, in fact, previously declined to enforce a

¹ The CPSIA phthalates are dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), di-(2-ethylhexyl) phthalate (DEHP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP).



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restriction on these six substances included in the CSPA (RCW 70.240.020) on the basis that it was preempted by the federal law and that the restriction would provide only “marginal opportunity to improve the safety of children’s products.”²

DOE has provided little rationale for reversing its previous determination to exclude the six CPSIA phthalates from the reporting rule except to indicate that “concerns about federal pre-emption are not as clear for phthalates as they are for lead.”³ In its response to comments, the Department also indicates that “all six phthalates meet both the hazard and potential for exposure criteria established in the law.”⁴ The Department’s decision to include the six CPSIA phthalates in the reporting rule is flawed for the following reasons –

- the reporting requirement is preempted by the CPSIA,
- the opportunity for improving the safety of children’s products as a result of the reporting requirement is no less marginal than it is for RCW 70.240.020, and
- not all of the CPSIA phthalates meet the hazard criteria established by the CSPA.

The Reporting Requirement is Preempted

As a result of the CPSIA requirements, toys and child care articles no longer contain DBP, BBP, or DEHP and DnOP, DINP, and DIDP can no longer be used to manufacture toys and child care articles that are small enough to be mouthed, subject to further review by an expert panel. While the decision by Congress was not based on a scientific evaluation, it was clear that Congressional concern about exposure to phthalates was based on the potential for exposure from products that might be placed in the mouth. Had Congress determined that the concern extended to phthalate use in all children’s products, it certainly could (and would) have expanded the scope of the CPSIA restrictions to include all products intended for children. They did not. Consequently, the Department’s Office of the Attorney General decided that the restrictions imposed by RCW 70.240.020 were preempted by the federal statute - even though the language of the CSPA references all children’s products. The Attorney General’s conclusion echoes that reached by the federal Consumer Product Safety Commission (CPSC) that the CPSIA’s “new lead limits for lead paint and lead content preempt state law as do the new provisions on phthalates and ATVs.”⁵

² WA DOE. Children’s Safe Product Act Report, Publication no. 09-07-015 (July 2009), at 2.

³ WA DOE. Children’s Safe Products Act – Reporting Rule, Summary and Response to Public Comment on Original Rule Proposal (May 4, 2011), at 4.

⁴ Id, at 4.

⁵ <http://www.cpsc.gov/about/cpsia/sect231.html>



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Reporting Would Provide No Opportunity for Improving Children's Safety

The Department also acknowledged that the potential for exposure from children's products other than toys and child care articles was minimal when it recognized in 2009 that the phthalate restrictions in RCW 70.240.020 provided only "marginal opportunity" to improve children's product safety. The proposal to inventory the use of the CPSIA phthalates under the proposed reporting rule provides even less opportunity for DOE, since no action is authorized by the CSPA.

DINP, DIDP, and DnOP Do Not Meet the Hazard Criteria

The inclusion of DINP, DIDP, and DnOP in the proposed reporting rule also fails to recognize that Congress requested a study of these three plasticizers to determine whether the interim CPSIA restrictions should be continued. It is premature for DOE to determine that use of these substances in children's products presents a hazard in advance of consideration by a Chronic Hazard Advisory Panel (CHAP) of experts convened by the CPSC in April 2010. The CHAP is expected to issue its report by April 2012 and CPSC is required by the CPSIA to act on the Panel's recommendations within 6 months of the report.

Among the many issues that the CHAP will consider is the potential hazard presented by the three phthalates subject to interim restrictions. In its own assessment, DOE has suggested that DINP and DIDP have been classified as "developmental toxicants" by the National Toxicology Program (NTP). The Department's summary grossly overstates the conclusions of NTP's Center for Evaluation of Risks to Human Reproduction (CERHR). In fact the CERHR concluded that -

The Expert Panel has *minimal* concern for unborn children due to ambient maternal exposure to DINP. Based on estimates of exposure to DINP in toys and other objects that children may mouth, the Expert Panel has *low concern* for potential health effects in children.⁶ (emphasis added)

The CERHR panel also concluded that it has minimal concern about DINP resulting in reproductive toxicity in humans. In a subsequent review conducted in 2003, the European Chemical Bureau (ECB) concluded that "there is at present no need for further information or testing or risk reduction measures beyond those which are being applied already" for all exposure scenarios, including infants exposed to DINP in toys.⁷

⁶ NTP CERHR Expert Report on Di Isononyl Phthalate. NTP-CERHR-DINP-00 (October 2000), at 32.

⁷ ECB. European Union Risk Assessment Report - 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and di-"isononyl" phthalate (DINP) (2003), at 251.



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The CERHR similarly concluded that it had “minimal concern” for children and fetuses due to exposure to ambient levels of DIDP.⁸ As for the potential exposure from toys, the CERHR indicated that it “cannot judge the potential health effects in children from mouthing of objects containing DIDP due to the lack of exposure information.” Elsewhere, however, the Expert Panel noted that it is reasonable to assume that exposure to DIDP is lower than exposure to DEHP, “based on the physiochemical characteristics of DIDP.”⁹

The CERHR also reviewed the information available for DnOP and concluded that “although all of the databases are limited or inadequate, the existing data do not suggest that DnOP is a potent developmental or reproductive toxicant in rodents.”¹⁰ The Expert Panel further noted that there are no known commercial uses for pure DnOP and that DnOP constitutes approximately 20% of the commercial mixture C6–10 phthalate.

The proposal to list DINP, DIDP, and DnOP as CHCCs under the CSPA is in stark contrast to the conclusions of the CERHR and expert panels convened elsewhere in the world to review the evidence for these substances.

DEP, DnHP, and Phthalic Anhydride Should Not Be Subject to Reporting

The PE Panel has previously commented to DOE on the hazard and exposure criteria used to evaluate substances for inclusion in the reporting rule and the application of those criteria to phthalic anhydride (PA), diethyl phthalate (DEP), and di-n-hexyl phthalate (DnHP). As neither DEP nor PA was included in DOE’s original rule proposal (October 2010), we had assumed that both had been removed from consideration and did not provide additional comments on these two chemicals. In light of their inclusion in the latest proposal, and the continued inclusion of DnHP, we wish to remind the Department of our previous comments on these substances.

PA is a product of phthalate metabolism and is an important chemical intermediate, with little potential for exposure to children. As it is only sold as an industrial intermediate, and the evidence for adverse health effects in laboratory animals is quite limited, inclusion of PA does not meet the CSPA criteria for inclusion. In fact, the Department’s rationale for the substance notes that the hazard evidence for PA is limited and adverse effects were only reported in laboratory animals at high doses. Regarding exposure, the Department cites a single reference from the Danish EPA regarding the presence of PA in wooden toys to conclude that the substance is known to be present in children’s products. DOE’s determination disregards the fact that none of the other cited sources (including NLM) indicate that PA is

⁸ NTP CERHR. Expert Report on Di Isodecyl Phthalate. NTP-CERHR-DIDP-00 (October 2000), at 26.

⁹ Id, at 7.

¹⁰ NTP CERHR. Expert Report on Di n Octyl Phthalate. NTP-CERHR-DNOP-00 (October 2000), at 19.



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present in children's products. The detection of PA in the data from the Danish EPA likely results from the breakdown of a resin product that may or may not be detected during the manufacturing process.

DEP also exhibits little biological activity. According to the recent review by the Australian Department of Health and Ageing¹¹, the lowest observable adverse effect level (LOAEL) for developmental effects was estimated at 1016 to 1375 mg/kg/day, with a no observable adverse effect level (NOAEL) of 197 to 267 mg/kg/day.¹² The inclusion of DEP in category 1 of the initial European Union's list of candidate substances for evaluation as endocrine disruptors (the "EU candidate list") does not indicate that the substance is an endocrine disruptor. The candidate list was developed as part of the EU Community Strategy for Endocrine Disruptors¹³ (the "EU Strategy") to establish a list of candidates "for further evaluation," as outlined in the third progress report published in November 2007.¹⁴ 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. In the case of DEP, inclusion on the EU candidate list indicates that there are data suggesting developmental effects which, as evidenced by the LOAEL and NOAEL, occur at relatively high exposure levels. The available data suggest that developmental effects in laboratory animals resulting from exposure to DEP occur at sufficiently high levels to minimize concerns about its endocrine disruption potential and to warrant removal of DEP from the CSPA list.

Some of the epidemiology studies cited by DOE as evidence of an association between DEP and adverse health effects have been discounted by the NTP's CERHR and European authorities. In the other cited studies, information on the level of DEP in biomonitoring samples is limited as it is combined with other phthalates to produce a composite score. These studies do not provide sufficient evidence for an association with DEP exposure, and do not support listing as a CHCC.

The Department's toxicity determination for DnHP is based on listing by NTP and the state of California (CA) as a reproductive toxin. The listing under CA's Proposition 65 resulted from "the formal identification of DnHP as causing male and female reproductive toxicity [in

¹¹ Department of Health and Ageing, National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Existing Chemical Hazard Assessment Report – Diethyl Phthalate (June 2008). (Available at (<http://nicnas.gov.au/Publications/CAR/other/phthalates.asp>.)

¹² DOE has incorrectly indicated in earlier background information that the LOAEL for DEP is less than 50 mg/kg/day.

¹³ The Strategy was adopted on December 20, 1999.

¹⁴ Commission of the European Communities, Staff working document on the implementation of the "Community Strategy for Endocrine Disruptors" - a range of substances suspected of interfering with the hormone systems of humans and wildlife SEC(2007) 1635 (November 20, 2007).



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laboratory animals] by the NTP.”¹⁵ Regarding the potential for DnHP to affect human reproduction and development, however, NTP concluded that there was “insufficient hazard and/or exposure data.”¹⁶ As evidence of its flawed logic, moreover, California’s Office of Environmental Health Hazard Assessment (OEHHA) established an allowable dose for DnHP that is among the highest established by the state (2,200 micrograms/day).

According to the NTP review, exposure to DnHP can only occur “as a component of commercial diisohexyl phthalate (DIHP), where it may attain concentrations of up to 25%; by migration from consumer products where it has limited use; and, by its presence as a minor component (less than 1%) of commercial C6–10 phthalates.”¹⁷ Additional information indicates that DnHP production is less than 1 million pounds¹⁸ and that use of both DnHP and DIHP is focused in the manufacture of automobile parts (*e.g.*, air filters, battery covers) and dip-molded products (*e.g.*, tool handles, dishwasher baskets).¹⁹

Available information also indicates that DnHP is not found in children’s toys. In its 2003 report, NTP noted that no studies “documented the detection of DnHP-containing compounds in children’s toys.”²⁰ DnHP also was not found in a subsequent survey of 100 soft vinyl products conducted in 2007 by Health Canada.²¹ Contrary to the Department’s determination, therefore, it is reasonable to conclude that DnHP is not found in children’s products and that the substance is unlikely to be ingested, mouthed, or sucked by children. Moreover, DnHP does not appear to be used in consumer or household products that might result in children’s exposure. Thus, children are unlikely to be significantly exposed to DnHP.

The Reporting Thresholds Should be Eliminated or Revised

Proposed WAC § 173-334-080 would require manufacturers to disclose the presence of a listed substance above the practical quantification limit (PQL) if it is intentionally added or

¹⁵ OEHHA. Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Di-*n*-Hexyl Phthalate (DnHP) (May 2008).

¹⁶ NTP Center for the Evaluation of Risks to Human Reproduction. NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di-*n* -Hexyl Phthalate (DnHP). NIH Publication No. 03-4489 (May 2003), at II-1.

¹⁷ *Id.*, at II-1.

¹⁸ EPA Inventory Update Reporting data for 2006. Available at <http://www.epa.gov/oppt/iur/>.

¹⁹ SRI Consulting. Chemical Economics Handbook Marketing Research Report – Plasticizer (November 2009), at 53.

²⁰ NTP CERHR (May 2003), at page II-2.

²¹ Canada Gazette, Part 1 – Notices and Proposed Regulations, Vol. 143, No. 25 (June 20, 2009). Available at <http://canadagazette.gc.ca/rp-pr/p1/2009/2009-06-20/html/reg3-eng.html>.



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above 100 ppm if it is a contaminant. This proposed requirement would place a large and unnecessary burden on manufacturers to test for the presence of substances in their products at levels that are far below any of potential relevance to children's health. Acceptable standards for *de minimis* amounts of substances already exist under the federal Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard and the European Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). There is no public health basis for requiring lower thresholds for reporting under the CSPA, particularly when the proposal would create a requirement for extensive testing of children's products. RCW 70.240.030 directs the Department to identify chemicals that are of high concern for children after considering the "potential for exposure to each chemical." It does not direct DOE to chase down every molecule of the substances that it determines to be of high concern.

The language of the statute does not direct DOE to establish an arbitrary and cumbersome testing requirement and, in fact, does not require that reporting thresholds be established at all. For the purposes of the state's inventory of CHCCs in children's products, in fact, merely requiring that manufacturers report whatever data they may have on the levels of CHCC's that are intentionally added to a children's products is likely sufficient. The proposal to test for these substances at the PQL is punitive and unnecessary. The proposal to test for contaminants, even if at a higher threshold, is equally unnecessary.

The CSPA was intended to establish a program whereby DOE could assess whether children were routinely being exposed to commercial chemicals at levels that may present a public health concern. It was not intended as a means to establish requirements that duplicate or contradict those of the federal government, to chase substances that have not been (or that are unlikely to be) found in children's products, to burden manufacturers with testing requirements, or to identify negligible levels of substances that may be present in children's products. We urge the Department to remove the eight phthalates proposed as CHCCs and to eliminate or revise the proposed reporting thresholds for substances ultimately identified as chemicals of high concern.

Please contact me at steve_risotto@americanchemistry.com or (202) 249-6727 if you would like to discuss the above information in further detail.

Sincerely,

Steve Risotto

Stephen P. Risotto
Executive Director



Grice, Joshua (ECY)

From: Ana Rivero [orevir25@gmail.com]
Sent: Tuesday, June 14, 2011 8:55 AM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Ana Rivero
5809 149th Ave SE
Bellevue, WA 98006

Grice, Joshua (ECY)

From: Cal Roberts [crobe86209@aol.com]
Sent: Monday, June 13, 2011 5:36 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

Dear John R. Williams,

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- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Cal Roberts
504 NE 139th Ave
Vancouver, WA 98684

Grice, Joshua (ECY)

From: Janna Rolland [jannarolland@hotmail.com]
Sent: Tuesday, June 14, 2011 11:54 AM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Janna Rolland
6227 34th Ave NE
Seattle, WA 98115

Grice, Joshua (ECY)

From: Rick Romito [stargazer0329@comcast.net]
Sent: Tuesday, June 14, 2011 8:14 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Rick Romito
4534 Fir Tree Way
Bellingham, WA 98229

Grice, Joshua (ECY)

From: Heather Rosewarne [schaubster@hotmail.com]
Sent: Tuesday, June 14, 2011 1:23 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Heather Rosewarne
3618 35th Ave S
Seattle, WA 98144

Grice, Joshua (ECY)

From: Gilbert Ross [rossg@acsh.org]
Sent: Wednesday, June 15, 2011 12:49 PM
To: Williams, John (ECY)
Subject: ACSH Statement on WA DOE Phthalate proposal
Attachments: Chemophobia-ScaredtoDeath.docx; ATT2310869.htm

Mr. John R. Williams

Washington State Department of Ecology

PO Box 4760

Olympia, WA 98504-7600

Dear Mr. Williams:

On behalf of The American Council on Science and Health (ACSH), I would like to submit the following comments regarding the Washington Department of Ecology's (DOE) proposal to list several phthalates on the reporting list for chemical of high concern to children in the Children's Safe Products Act (CPSA).

We have noticed in our outreach to media and policymakers that there seems to be, recently in our country, an irrational fear of chemicals, what we call "chemophobia." This phenomenon is running rampant across the United States and leading us down a dangerous and irreversible path where fear drives policy. If you look at the facts, the science does not support listing phthalates as chemicals of concern. Contrary to misinformation provided by the media and other sources, phthalates enhance our well-being and make possible our standard of living in the twenty first century. Furthermore, the listing of these six phthalates (DIDP, DINP, DBP, BBP and DNoP) in the proposed regulation could stigmatize this class of chemicals and lead to less studied and unknown alternatives being substituted into consumer products.

"Scared to Death: How Chemophobia Threatens Public Health"

Attached you will find Mr. Jon Entine's position paper — written on behalf of ACSH — that discusses how chemicals came to find such a villainous and conflicted role in the 21st century. Safety is a relative concept that depends on frequency, duration and magnitude of exposure. The current culture of paranoia about all chemicals is unhealthy and can lead to serious health concerns if fear becomes a policy drive. We can all agree that testing and verifying the safety of chemicals is essential; however, automatically assuming that alternatives are better for human health than the chemicals they would replace is a dangerous and unsupported line of thought. Often alternatives have not been scrutinized and studied to the same degree as the chemicals they would replace and would cause more harm than good. The chemophobia that our country faces is causing the opposite of its intentions: a decrease in public health standards via an unwarranted increase in chemical regulation.

Reviewing the science on phthalates will show that listing phthalates as chemicals of high concern for children is not justified for the following reasons:

Phthalates Have Been Proven To Be A Safe Class Of Compounds

Phthalates are a class of chemicals used over the past fifty years or more, in thousands of everyday products. They enhance the well-being of individuals in ways both large and small, such as being included in oxygen masks on airplanes and used in lifesaving equipment in hospitals including as blood bags and IVs. Across the board, phthalates are some of the most extensively studied chemicals and the data tells the story. These chemicals are proven safe for their intended use and are an integral part of the plastics industry in Washington because they make plastic products more durable, stronger, and less brittle and therefore safer for consumer use. If these six phthalates are listed as 'chemicals of concern' it could potentially lead to substitution of alternative plasticizers which is troubling. The alternatives have not been subject to extensive scientific studies and their use and widespread impacts are unknown, whereas phthalates have been used and studied for several decades and have credible science behind them to support their safe usage.

It's The Dose That Makes The "Poison"

Average Americans, in their daily lives, use plastic products that contain phthalates. While researchers have long recognized our bodies do in fact absorb some small amounts through handling of such items, negligible exposure does not translate into adverse health effects. According to biomonitoring data collected by the U.S. Center for Disease Control, exposure to phthalates is very low and when levels of phthalates are in fact detected, they fall within safety levels established by the U.S. federal government. Moreover, modern science allows researchers to measure trace amounts of substances in the body down to parts per trillion: finding such levels does not mean that they pose any harm. Further, research has proven that these phthalates typically pass through the body through natural excretion in less than a day because of their chemical composition and half-lives.

Alternatives Are Less Studied

Listing phthalates as chemicals of concern to children could lead to numerous unintended consequences. First, such a policy would essentially blacklist phthalates and send a message to manufacturers that they should find replacements. That's where the problems begin. Switching to alternative plasticizers is not a simple process or an easy fix. Alternative plasticizers have not been reviewed by the appropriate government agencies and very little is known in the field about their toxicological profiles. Subsequently, proven-safe chemicals would be phased out in the name of safety yet replaced with unfamiliar chemicals that are potentially dangerous to consumer health and safety.

For these reasons, the American Council on Science and Health urges the Washington State Department of Ecology to reconsider the listing of the six phthalates in the proposed regulation. Listing these substances as "chemicals of high concern to children" would only stigmatize these chemicals to no one's benefit, and demonize a class of chemicals that has already been deemed safe for its intended uses and potentially endanger the very people the law is meant to protect.

Sincerely,

Elizabeth M. Whelan, Sc.D., M.P.H. President Gilbert L. Ross, M.D. Medical Director

The American Council on Science and Health

1995 Broadway New York, NY 10023

Gilbert Ross M.D.
Medical Director
The American Council on Science and Health
1995 Broadway
New York NY 10023
212-362-7044 x242
rossg@acsh.org
Twitter: @ACSHorg
fax 212-362-4919
Please visit www.acsh.org and www.healthfactsandfears.com

**SCARED TO DEATH:
HOW CHEMOPHOBIA THREATENS PUBLIC HEALTH**

Presented by
The American Council on Science and Health

By Jon Entine

CHE•MO•PHO•BI•A : the irrational fear of chemicals

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EXECUTIVE SUMMARY

When Pamela Davis was pregnant with her daughter Meaghan, she started to worry about contamination from lead paint in her Hoboken, New Jersey home. She read stories about chemicals in baby dolls, pots, shower curtains and carpets. An article on the Internet warned that sippy cups were dangerous. A friend told her that the bright pink baby pajamas she had gotten as a gift were treated with toxic flame-retardants. Soon her entire nursery seemed to pose mysterious threats to her unborn baby. Pamela felt trapped.

If news stories and the Internet are to be believed, the dangers from chemicals are increasing, cancer stalks us at every turn and our children are vulnerable. Synthetic chemicals are essential for modern life, but our views of them are conflicted. We rely on chemicals to improve human health. Pharmaceuticals keep us healthy. Plastics are found in everything from toys to cars to medical supplies. Pesticides and herbicides boost food production and quality. It's impossible to conceive of life in the 21st century without the materials and fuels that synthetic chemicals have made possible. But from soap to sunscreens, drugs to DDT, we are faced with an endless stream of confusing messages about the safety of chemicals we come in contact with everyday. The synthetic ingredients that make up many products suggest the unknown, and like many of us, Pamela Davis processes that as fear. "Once you're aware of one thing it just spreads and you start questioning everything," she said. "You can drive yourself absolutely crazy trying to keep your baby healthy."

Considering the conflicting narratives, the public has difficulty distinguishing between useful and benign substances in products and those that could pose dangers when misused. Highly publicized reports of environmental, chemical and pharmaceutical catastrophes—from the Exxon Valdez and BP oil spills to Bhopal to thalidomide—are mixed interchangeably with

exaggerations and scare stories about chemicals found in common plastics or in our homes. Belief in the relative benefits of chemicals, trust in the industries that produce them and confidence in government regulators have never been lower. Corporations that produce chemicals are often portrayed as greedy and indifferent. Questions persist about the government's ability to exercise its oversight responsibilities.

The perceived risk posed by common chemicals has grown even as research has raised doubts about the assumed links of many chemicals to cancer. Lifestyle factors like a lack of exercise, smoking, alcohol consumption and eating habits that lead to obesity contribute far more to the overwhelming majority of cancers, while the misuse of chemicals is believed to trigger only a few percent of the cases at most. Yet, the chemophobia epidemic keeps gaining momentum.

How does the public adjudge hazard, safety and risk? How safe is safe? Media perceptions and government regulations are often shaped by a fervor fed by misconceptions about the widespread dangers of common chemicals. An illusion has developed that chemicals can be divided into categories of "safe" versus "unsafe." But any substance, even food and vitamins, can be harmful if we consume too much of it. Safety is relative, depending on the frequency, duration and magnitude of exposure. This obsession with chemicals is unhealthy. Serious health challenges need to be forcefully confronted, but the resources devoted to challenging and removing relatively innocuous chemicals and developing substitutes—substances that have often not been scrutinized as much as the chemicals they would replace and thus confer an illusion of safety—divert us from addressing known health risks. This chemophobia can result in the opposite of what was intended: a decrease rather than an increase in public health.

INTRODUCTION

The public misunderstanding of chemicals and risk has arisen due to variety of factors: advances in analytical chemistry allowing the detection of ever smaller amounts of substances; evolution of the Internet and social media; emergence of environmental advocacy organizations staffed with committed activists but often few scientists; uncritical or outright biased reporting about claims that synthetic chemicals are inherently risky; industry capitulation to campaigns against their products; government inclination to respond to exaggerated claims in politically safe but scientifically unsound ways; and the erosion of public trust in authority, including of government, industry and the scientific community.

Chemical manufacturing is estimated to be a \$3 trillion global enterprise. The U.S. Environmental Protection Agency (EPA) estimates that there are 84,000 synthetic substances in use in the world today. Chemicals are used to make a wide variety of consumer goods, as well as products for the medical, agricultural, manufacturing, construction and service industries. The boom started in the early 20th century and accelerated in the 1920s and '30s with advances in technology leading to the creation of new forms of plastics, including nylon and synthetic rubber made from petrochemicals. The use of newly developed chemicals played an important role in the Allied victory in World War II.

In the postwar years, a country on the cusp of sustained prosperity embraced scientists and industry as architects of innovation. The 1950s brought affluence to more Americans, leading to an increased demand for consumer goods, from energy and detergents to plastic, rubber and fibers. A sophisticated pharmaceutical industry arose. Agribusiness grew rapidly in response to

both public concern about feeding the world—the Green Revolution was made possible by the advent of pesticides and synthetic fertilizers—and the desire for fruits and vegetables year round. It was an era of growing abundance and chemicals were viewed as essential components of this consumption revolution.

But the complexity of modern life gradually intervened. Dramatic growth laid bare the inadequacy of certain public protections. Corporations, the engines of progress, were also the main source of industrial pollutants that fouled our air, water and soil. Legitimate concerns emerged over the use of chemicals on farm products and in the making of consumer goods and drugs. Highly sophisticated detection techniques that measure minute levels of toxic chemicals in blood and urine helped fan anxiety. Fifty years ago, science could isolate a trace chemical from a capful dumped into a swimming pool; now we have instruments that can identify that same chemical in the parts per trillion in Lake Erie.

In response to the growing impact of chemicals, numerous federal agencies, most notably the EPA, which regulates chemicals in the environment, and the Food and Drug Administration (FDA), which regulates foods and drugs, were founded or expanded. The Centers for Disease Control (CDC) and the Occupational Health and Safety Administration (OSHA) also evaluates potentially hazardous chemicals, particularly those that cause, or might cause, cancer. These agencies have evolved in a climate of increasing public mistrust to address the growing complexity of modern production and consumerism. Most industrial countries have comparable oversight bodies. Today, there are 170 synthetic chemicals or exposure circumstances that have been classified by one such agency, the International Agency for Research on Cancer (IARC), as known or probable human carcinogens.

Numerous chemicals—natural and synthetic—have been identified in the environment as dangerous at elevated levels of exposure and for which genuine caution is warranted. For example, lead exposure can lead to neurological problems, including seizures, coma or death, which is why its use is tightly regulated. Many workers exposed to asbestos, another natural substance, developed lung disease and cancer because its toxic effects were not known, regulations were lax, ventilation systems were inadequate and they did not wear protective clothing. Workers who handle almost any chemical in high enough concentrations need special protections. But even a highly toxic chemical should not necessarily be banned outright; that decision should be based on where and how a chemical is used and at what concentrations. Its potential risks must be balanced against its demonstrated benefits.

The public controversy, however, exists over relatively common chemicals found at minute levels supposedly lurking in our foods and in everyday consumer products. Lurid headlines, such as “Alarming Body Burden Results: Tests Reveal 300 Chemical Compounds in Newborn Babies” (Lance 2008) or “89 of 116 Chemicals Detected in Americans’ Blood and Urine” (Brown 2009), used alarmist language. Although advocacy groups play an important role in focusing public attention on potential environmental hazards, some NGOs (non-governmental organizations) consistently exaggerate the threats, going so far as to portray our houses, schools, hospitals and workplaces as toxic cauldrons. By their measure, questionable substances can be found in meats and fish, on fruits and vegetables. The bottled water industry, created because people feared contaminants endanger our tap water, now finds itself under scrutiny for selling water in plastic containers made with chemicals that modify our hormones. Cookware and plastic wrap, sippy cups and the cans used to package long-shelf life foods are portrayed as serious

hazards. Danger looms in cosmetics, toothpaste and cleansers. Carpets, drapes and cabinetry are sources of alarm. The list goes on and on.

While scientists may scoff at this caricature of risk and the implication that chemicals are inherently dangerous, such stories are the calling card of many advocacy campaigns and are given credence in the media. Even as you read this, people are snapping up the latest scare treatise, *No More Dirty Looks*, which, according to *Time* magazine, “unmasks the toxic ingredients in mainstream chemicals.” (Walsh 2010)

Even as the hard evidence suggest Americans have never been safer when it comes to exposure to chemicals and drugs, many people mistakenly believe we face more environmental hazards now than at any point in history. That’s understandable. Over the years, the public has been traumatized by oil spills; the thousands of deaths and injuries associated with the methylmercury contamination of Minamata Bay in Japan by the Chisso Corporation from 1932 to 1968; the explosion at a Union Carbide pesticide plant in Bhopal in 1984; and occupational exposures to vinyl chloride, benzene and aniline dyes. The problems caused by the drug thalidomide, which was withdrawn in 1961, left deep scars. Numerous drugs have been withdrawn in recent years because of health concerns such as cardiovascular toxicity (e.g. Vioxx/Rofecoxib; fenfluramine, with fentermine called Fen-phen), liver damage (e.g. Trovan/Trovafloxacin) or other ill effects, some not sufficiently identified during trials.

Less clear-cut are controversies over exposure to environmental chemicals such as Agent Orange (a Vietnam-era defoliant that contained a dioxin compound), PCBs (polychlorinated biphenyls, found in industrial fluids) or the pesticide DDT (dichlorodiphenyltrichloroethane), in which

scientists have modified or even reversed their assessments of toxicity. Equally problematic are reports about the purported dangers of chemicals that we encounter regularly in common products, such as BPA (bisphenol A) and phthalates used in plastics; the industrial surfactant PFOA (perfluorooctanoic acid also known as C8), PBDE (fire retardant compounds polybrominated diphenyl ethers) and atrazine, an herbicide.

Unfortunately, scientific literacy in the United States is abysmal. On the 200th anniversary of Charles Darwin's birthday, a Gallup poll found that only 4 in 10 Americans believed in the science of evolution (Gallup 2009). Many journalists do not have the training or sophistication to put complex science issues in context. Media stories and Web posts often demonize commonly used chemicals that scientists and regulators have found to be perfectly harmless. Unwarranted fears are intensified by the myth that "nontoxic" and "green" chemicals exist that can replace the allegedly risky ones. These narratives are bolstered by the mistaken belief that the presence of a synthetic chemical at any concentration is dangerous. The trace of a chemical in the air, water or even in our urine or blood is in itself not necessarily something to be concerned about. The Renaissance physician Paracelsus crystallized the central tenet of toxicology, loosely translated as, "The dose makes the poison."¹ Our bodies and the environment are made up of thousands of chemicals, natural and synthetic, that theoretically could harm or kill us. Every chemical can be dangerous if the level of exposure is high enough. We need to weigh the benefits that a chemical might bring against its potential toxicity—and at what dose or level of exposure.

There are toxic threats in our environment and it's important to identify them and take

¹ The German axiom, *Alle Ding' sind Gift, und nichts ohn' Gift; allein die Dosis macht, daß ein Ding kein Gift ist*, translates more directly as, "All things are poison and nothing is without poison, only the dose permits something not to be poisonous."

appropriate action, but the picture painted in some quarters far overstates the actual dangers. Regulation of chemicals is stricter and more effective than it's ever been. There have been significant advances in technology and ways of handling chemicals by industry. Only a trickle of new drugs makes it to market each year. In the case of pesticides, for example, the crop chemical industry estimates that only one in 139,000 new compounds survive the gauntlet from the chemist's laboratory to the farmers' fields. Each potential product that makes it into production undergoes some 120 separate tests taking 8 to 10 years at a cost of as much as \$184 million (CropLife America 2010).

The politics of contested science can be a messy business for everyone. The motivations of industry and self-proclaimed environmental white knights are not always transparent. Intentions are difficult to deconstruct when ideology, financial incentives, academic reputations and public attention are in play. While scientists who accept private funding, even for a study of a substance that's not at issue, risk being labeled by advocacy groups and academic scientists as "corrupt," NGOs and university scientists who endorse exaggerated assessments of chemical risk are sometimes positioning themselves for government grants or publicity.

Chemophobia is rising even while the actual danger of chemical contamination or harm from everyday exposures, particularly in the workplace, has decreased sharply over the years. The very word "chemical" has become a hot button. A recent national poll by the University of Michigan found that the public rates "chemicals in the environment" almost as big a concern as teen pregnancy, alcohol abuse and child neglect, and far more dangerous than depression or school violence (University of Michigan Child Health Evaluation and Research Unit 2010). Yet, researchers have found that more than 70 percent of cancer cases can be linked to smoking and

poor eating habits that lead to obesity, while exposure to chemicals causes only a few percent of the cases at most (Doll and Peto 1981). Perceptions about chemicals have become so distorted that many people are willing to forgo the unquestioned benefits of their use, such as in vaccines, because they believe that they could poison their children. The result is a society that is increasingly wary of chemicals and science in general, and supportive of the removal from the market of many useful and in some cases irreplaceable chemicals—even when there is no evidence that they pose serious risks and the substances that replace them are often untested. Moreover, out of political expediency, the government is often forced to respond to public scares by spending millions of dollars on amelioration, research and mitigation—money that often goes to organizations that have a financial incentive to maintain there are problems. If it's later perceived that this money was ill used, the credibility of both scientists and the government are compromised—and the public interest was not served.

THE RISE OF THE ENVIRONMENTAL MOVEMENT

In the early years after WWII, the benefits of industrial chemicals and the positive role of industry in general, especially in improving the quality of life, overshadowed environmental concerns. The agricultural revolution was transforming the world, bringing unanticipated levels of self-sufficiency and prosperity. Synthetic pesticides were hailed as modern miracles in the battle against pests, weeds and hunger.

However, public attitudes toward what were then called conservation issues began to change. Pollution emerged as a serious problem. A noxious mix of sulfur dioxide, carbon monoxide and metal and coal dust descended on the Pennsylvania town of Donora in 1948 and London in 1952, killing and sickening thousands. Los Angeles was regularly in the grip of a smoggy shroud. Fear of cancer—from pollution, radiation, agricultural chemicals, mysterious microbes in our food, water, whatever—escalated. It was the beginning of a long, gradual decline in the confidence of Americans in industry and the ability of government to protect them (American National Election Studies 2009).

Evolution of the FDA

Growing concerns in the 1950s spurred legislative action to amend the quarter-century-old Federal Food, Drug and Cosmetic Act (FDCA) from which the FDA had emerged. Congress had passed the FDCA in 1938 after the poisoning deaths of more than 100 patients who ingested sulfanilamide medication in which diethylene glycol was mistakenly used to dissolve the drug and make a liquid form. “Safe tolerances” had been established for “unavoidable poisonous substances” but the rules were vague because of the rudimentary science of the times. It became clear that the old laws did not adequately address the consequences of the surge in the use of

complex chemicals used on farms and in foods and their possible implications for human health.

In 1954, Congress passed the Miller Pesticide Amendment, which set safe tolerances for pesticide residue on raw fruits and vegetables. The Food Additives Amendment, passed four years later, in 1958, required premarketing clearances for substances intended to be added to food. Prior to that legislation, the FDA had to prove an additive was potentially harmful before it could obtain a court order banning its use. This law shifted the responsibility to prove safety to the manufacturer, even though “safety”—the absence of risk—cannot be “proven” by science.² The amendment included the Delaney clause that effectively banned any food additive that was shown to cause cancer in any species:

“No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or laboratory animals or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animals.” (Merill 1997)

This law broke new ground as it invoked science as the way to assess risk, but it was problematic for other reasons. The language of the clause implies that the results of cancer studies in nonhuman species, such as rodents, could be assumed to apply to humans, thus resulting in bans when only minute levels are found. The Delaney clause also contradicts the central rule of toxicology: “the dose makes the poison.” It established the scientifically suspect notion that dose doesn’t always matter. In effect, the government legitimized the use of very high-dose studies in which animals were fed hundreds or even thousands of times more of a chemical than humans

² The limit of detection always determines the extent of what we mean by safety, and we cannot prove the absence of something only its presence.

could possibly consume, without clear evidence that the effect on rodents correspond to the effect of low dose exposure on humans. (The Delaney clause remains operative today, but is followed only in part because evolving analytical techniques enable chemists to detect chemicals of interest in food or water at levels a billion to a trillion times lower than was possible in 1958. For example, if it's shown that a regulated food additive does not cause cancer but contains a trace level impurity added during processing that does induce cancer when tested separately, the *de minimis* trace constituent would not result in the additive being banned.)

The new near zero-tolerance legislation opened a proverbial can of worms. In short order it led to the country's first national cancer panic. Only weeks before Thanksgiving 1959, miniscule traces of a synthetic herbicide that had been found to cause cancer in rodents exposed to high doses were detected in cranberries grown in Oregon and Washington. That set off a media scare. In a panic, the Secretary of Health, Education and Welfare announced:

“The Food and Drug Administration today urged that no further sales be made of cranberries and cranberry products produced in Washington and Oregon in 1958 and 1959 because of their possible contamination by a chemical weed killer, aminotriazole, which causes cancer in the thyroids of rats when it is contained in their diet...”

The sale of cranberries crashed that holiday season, devastating the industry. It was pointed out that one would need to eat 15,000 pounds of cranberries every day of one's life to match the dose the rodents were fed, but reason was lost in the hysteria of the moment. The fears subsided when presidential hopefuls John Kennedy and Richard Nixon made a point of eating cranberries and

respected scientists spoke out to reassure the public (Life 1959).

The cranberry scare of 1959 was followed two years later by a legitimate crisis involving thalidomide, a sedative. Responding to one of the biggest medical tragedies of modern times, the government ordered the drug withdrawn from the market in 1961 after it was found to cause birth defects (Lenz 1998). The incident led to much stricter testing on pharmaceuticals and pesticides before they could be licensed and fed concerns that federal agencies might not be up to the task of overseeing potentially dangerous drugs and chemicals.

Silent Spring

The catalyzing event for the modern environmental movement was the publication of Rachel Carson's *Silent Spring* in 1962 (Carson 1962). Carson had worked for years at the U.S. Fish and Wildlife Service, eventually becoming the chief editor of that agency's publications. She argued in her book that uncontrolled and unexamined pesticide use was harming and even killing not only animals and birds, but also humans. She indicted industry and the federal government. The book kicked off a public dialogue about the impacts of chemicals on wildlife and the environment.

Carson's primary target was dichlorodiphenyltrichloroethane (DDT), an insecticide then in widespread use in areas of the world where malaria was endemic, because of its effectiveness in controlling disease-carrying mosquitoes. Testing by the U.S. Public Health Service and the FDA's Division of Pharmacology had found no serious human toxicity from DDT, and the chemical's inventor was awarded the Nobel Prize in 1948. At the time of the book's publication, DDT had become an essential health weapon around the world, saving millions of lives each year. Carson alleged that DDT was harming eagle and falcon eggs by thinning shells, which

could lead to fewer hatchlings. The title of her book was meant to evoke a spring season in which no bird songs could be heard because they had all vanished as a result of pesticide abuse.

In 1955 the American Cancer Society had predicted, “Cancer will strike one in every four Americans rather than the present estimate of one in five.” Seven years later, Rachel Carson would cleverly call her chapter on DDT and human cancer “One in Four.” Even people who did not care much about wildlife cared a lot about their own health and the health of their children. The greatest cancer threat, of course, is not from environmental chemicals but from cigarettes. Ironically, one of Carson’s primary sources was Wilhelm Hueper, chief of environmental cancer research at the National Cancer Institute (NCI) and one of the leading researchers in this area. Hueper was so convinced that trace exposures to industrial chemicals were the major cause of cancer in humans that he focused far less attention on tobacco usage, which is now recognized as a far greater threat. The dangers of tobacco were addressed comprehensively in the 1964 report by the U.S. Surgeon General causally linking smoking to lung cancer (Public Health Service 1964). The tobacco industry responded defensively with a powerful disinformation campaign, further undermining the public’s trust in corporations. That helped give credence to one of the central arguments of the environmental movement: industry was putting profits ahead of the health of people and the planet.

Silent Spring may have been thin on the science of chemicals and cancer but it was a powerful and emotional tour-de-force for those who believed that environmental issues were being overlooked. The 1960s were marked by a growing sense that the government and “Corporate America” were aligned and indifferent to environmental challenges. A perception took hold that man himself as well as trees and wildlife were an endangered species. The cognoscenti began

using an arcane term—ecology—in reference to a science of the environment, then still in its infancy.

As the decade drew to a close the Nixon Administration, already on the defensive because of Vietnam and a budding recession, found itself dealing with a number of high profile environmental challenges. When people witnessed on television the defoliation chemicals used in the jungles of Indochina, they became even more receptive to the environmental concerns advanced by Carson, consumer advocate Ralph Nader and others. Legitimate concern over air and water pollution began spreading in widening eddies. Federal regulators faced increasing pressure from a skittish public to respond to concerns over the environment and public health even in cases where the science did not justify intervention.

What's now often referred to as the "cyclamate scare" is a case in point. The popular artificial sweetener cyclamate, which had been designated as GRAS (Generally Recognized as Safe) since the 1950s, came under scrutiny in 1969, when a study found that eight out of 240 rats fed a mixture of saccharin and cyclamates developed bladder tumors. The rats had been fed high-dose levels comparable to humans ingesting 350 cans of diet soda per day for months. No other labs could reproduce these findings, which are in themselves of questionable significance. But modest concerns erupted into a national scare when an FDA scientist went on network television displaying pictures of chick embryos that suffered from severe birth defects after being injected with cyclamates (Henahan 1977).

With the Delaney clause in effect, government regulators believed they had little wiggle room. "We recommend the cyclamate ban because of the law, not because there is any reason to

believe that it causes cancer in man,” said one of the reviewers (Science News 1969). Spurred by a public outcry orchestrated by consumer activists, including Nader’s Public Interest Research Group, the FDA banned cyclamates (Price 1970). The success of the anti-cyclamate campaign led to the publication of the Nader-inspired book, *The Chemical Feast* (Turner 1970), which raked the FDA for not regulating “dangerous” food additives.

The alarmism served to reinforce the unscientific standard that high-dose studies on animals are automatically applicable to humans. It also legitimized the use of scientists to endorse politicized policy judgments, a disturbing but persistent pattern that undermines the confidence of the public in supposedly independent scientific experts. Cyclamates remains banned from food products in the United States although the FDA has since publicly stated that a review of all available evidence does not implicate the sweetener as a carcinogen in mice or rats.

Birth of the EPA

Among the burning issues of the day were the alleged threats of DDT and the emerging concern that population growth posed a catastrophic threat to the future of the planet. One of the first of the new wave of environmental advocacy groups, the Environmental Defense Fund (now known as EDF or Environmental Defense), was founded in 1968 to specifically target DDT and helped launch legal actions against the use of the pesticide.

The bestselling 1968 book *The Population Bomb*, by entomologist Paul Ehrlich, blamed uncontrollable growth in what was then called “The Third World” as the seed of all environmental problems. He also railed against DDT. The issue of restricting population growth played into the debate over DDT in a disconcerting way. The public was confronted with Ehrlich’s (erroneous) conviction that hundreds of millions of people would starve to death in

coming decades because of overpopulation. The issue of withdrawing anti-malarial programs as a means of population control was broadly discussed and debated. In his book, Ehrlich himself appeared to “blame” DDT for saving lives, exacerbating the overpopulation problem:

“The introduction of DDT in 1946 brought rapid control over the mosquitoes which carry malaria. As a result, the death rate on the island [of Ceylon] was halved in less than a decade. ... Death control [DDT use] did not reach Colombia until after World War II. ... Each child adds to the impossible burden of a family and to the despair of a mother.” (Ehrlich 1968) (Ehrlich 1968) (Ehrlich 1968)

However unintended, the exaggerated fears about population growth and environmental degradation led many conservationists to propose the unthinkable. They actively began debating Ehrlich over what he called a “death rate solution” to these combined problems. A debate erupted over banning DDT as a way to cull the world population through denying life-saving spraying of agricultural chemicals (Roberts 2010).

In response to growing public concern about a variety of environmental challenges, the White House set up a Citizens’ Advisory Committee on Environmental Quality in 1969. That was followed by the signing on January 1, 1970 of the National Environmental Policy Act, which led to the formation of the EPA. The agency assumed regulatory control of pesticides from the U.S.DA. Not surprisingly, deciding the fate of DDT was the first task of the newly created EPA. Scientists urged caution. The National Academy of Sciences reviewed the evidence in 1970, declaring, “In little more than two decades, DDT has prevented 500 million human deaths due to

malaria, that would otherwise have been inevitable.” The EPA hearing examiner, Judge Edmund Sweeney, who listened to eight months of scientific testimony about the risks of DDT, came to a similar conclusion about its benefits, found little scientific evidence of its potential harm and recommended against a ban. “DDT is not a carcinogenic hazard to man,” he wrote:

“... DDT is not a mutagenic or teratogenic hazard to man. The uses of DDT under the registration involved here do not have a deleterious effect on freshwater fish, estuarine organisms, wild birds or other wildlife. The adverse effect on beneficial animals from the use of DDT under the registrations involved here is not unreasonable on balance with its benefit. The use of DDT in the United States has declined rapidly since 1959. The Petitioners have met fully their burden of proof. There is a present need for the continued use of DDT for the essential uses defined in this case. ... [N]ecessary replacements would in many cases have more deleterious effects than the harm allegedly caused by DDT.” (EPA 1972b) (EPA 1972b) (EPA 1972b)

Two months after the Judge’s hearings, EPA Administrator William Ruckelshaus, facing tremendous pressure from the media and NGOs, set aside the Judge’s findings and announced a broad ban on DDT. He cited the results of high-dose studies in rodents and invoked the principles outlined in the Delaney clause, which until that time had only been used in assessing the carcinogenicity of food additives. The likelihood that a ban would cost lives, which could have been assessed by cost-benefit or risk-risk analysis, was not considered. When it came to chemicals, perceptions and not scientific evidence was now driving the regulatory system. Today, 40 years after DDT was phased out, there is still no persuasive evidence that it is a human

carcinogen or can be held responsible for widespread harm to wildlife.

ENVIRONMENTAL RISK

The first Earth Day was held in 1970 shortly before the founding of the EPA. With pollution and the environment front and center in the public's mind, Congress responded by passing laws and launching new regulatory agencies. Key was the passage of the Toxic Substance Control Act (TSCA) of 1976. TSCA set up guidelines giving the government authority to determine if industrial chemicals present “an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards” (EPA 2010). It specifically targeted polychlorinated biphenyls (PCBs). Over the years, the core statute has never been reauthorized or amended, but new oversight responsibilities have been added to regulate four additional chemicals: chlorofluorocarbons, dioxin, asbestos and hexavalent chromium. TSCA included a cost-benefit clause requiring that the government's authority should be exercised “in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation.”

In the late 1970s and early 1980s, two dramatic incidents—at Love Canal, New York, and at Times Beach, Missouri—focused the attention of the U.S. public on industrial chemicals in the environment. In 1978 the area around Love Canal, a neighborhood near Niagara Falls, was found to be contaminated by a variety of chemicals—21,000 tons of toxic waste buried by the Hooker Chemical Company. The public was soon inundated with stories that children born in the community had high rates of birth defects and cancer (Heath, et al. 1984). A subsequent state-of-the-art study by the CDC and two other national laboratories rejected the publicly accepted claim that the toxins caused serious genetic abnormalities or any marked rise in disease. “This [study] suggests that no specific relationship existed between exposure to chemical agents in the Love

Canal area and increased frequency of chromosome damage,” the study asserted (Boffey 1983).

In 1982, the news was filled with reports that concentrated levels of dioxin had been discovered throughout the town of Times Beach. Later, PCBs were also found in the soil. Panic spread through the town, with every illness, miscarriage and death of an animal attributed to the chemicals. The EPA ordered an evacuation in 1983 and eventually declared it uninhabitable (Sun 1983). As concerns mounted, President Ronald Reagan formed a dioxin task force. At the time, dioxin, which was being blamed for a variety of illnesses in Vietnam veterans, was labeled as “the most toxic chemical synthesized by man,” based on high-dose studies in guinea pigs.

Subsequent research on the effects of dioxin on humans and other mammals led to a revised belief that its toxic effects are limited. No illnesses in Times Beach were ever linked to the presence of chemicals. Many experts question whether the razing of the town was necessary, citing the example of Seveso, Italy, the site of a disaster in 1976 that exposed residents to far larger levels of dioxin than those found in Times Beach and whose subsequent cleanup allowed the city to continue to exist. The Love Canal incident led directly to the 1980 passage of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly known as Superfund (U.S. Congress 1980). Superfund not only sensitized people to the widespread nature of chemical contamination of soil and groundwater but also led them to recognize that hazardous wastes were not only produced by industrial facilities but also by individuals in their homes, as a number of Superfund sites were local landfills. Battles over what to do with landfills lasted years and in some cases decades. The designation of Superfund sites underscored a belief in the ineptness of government and inflamed the perception that the public was not being adequately protected.

Responding to growing concern about chemical contamination, some states and localities convinced that the federal government was not acting proactively enough, took their own legislative actions. In the most striking example, in 1986 Californians voted for Proposition 65, the Safe Drinking Water and Toxic Enforcement Act, which ushered in a sweeping regulatory process for identifying and publicizing “toxic chemicals” (California Office of Environmental Health Hazard Assessment 2010). Proposition 65 requires the governor to publish a list of potentially dangerous chemicals. This list, which now includes hundreds of chemicals, many of which are not harmful at typical exposure levels, must be updated at least once a year. It has led to almost ubiquitous signs in gasoline filling stations, tire stores, workplaces, retail establishments (e.g. Macys, Home Depot) and even at airport boarding ramps warning that everyday products or chemicals are “known to the state of California to cause cancer, birth defects or reproductive harm.” The net effect initially was to stir anxiety among Californians and open up opportunities for class action suits, without any measurable benefits to public health.

Carcinogenic Risk

Until the 1960s, the standards used by the government to determine safety levels and manage risk were hopelessly imprecise and subjective. To establish safe levels for substances in the air, water or soil, regulators needed to move from the black/white qualitative approach of either allowing or banning a substance to a quantitative approach of determining how much of each substance might be allowable in each environmental situation. As the health focus on cancer and the fears associated with chemicals escalated, noted University of California at Berkeley chemist Bruce Ames invented a quick, inexpensive test (now known as the Ames test) to evaluate toxicity. His test determines if any chemical of interest might cause mutations in the DNA of

bacteria *in vitro* (in a controlled environment, such as in a test tube or Petri dish). If mutations were observed then that particular chemical was considered likely to be a carcinogen in lab animals.

The Ames test and the development of rodents modified to be cancer-prone led to an ultra-cautious toxicological evaluation system and chemical regulatory process. Over the years, what many scientists believe is a convoluted multi-stage model has been developed to extrapolate animal risk to people:

(1) Scientists do a biological assay (the Ames test) on some pesticide, food additive, preservative or other chemical to find out if it is mutagenic. It shows whether the DNA of the bacteria is altered in a significant way.

(2) If the chemical is confirmed as mutagenic, studies are then undertaken to determine what is called the “maximum tolerated dose” (MTD) of this chemical in rats or mice. The MTD is the amount of the chemical that almost kills a rodent (or almost achieves another parameter, such as suppressing body weight.) It is a dose that, depending on the particular chemical, can be thousands to millions of times higher than a human could ever ingest in a lifetime.

(3) Next, the rodents are fed just 10 percent less than the maximum tolerated dose daily for their entire one- to two-year lifetime.

(4) However, many chemicals cannot be fed to rodents because the substances are so noxious at the dosages given. So scientists often use *gavage* (forced feeding into the

animal's gut every day, often by injection), which is not how humans are exposed to the chemical, compromising the meaningfulness of the test.

(5) After a year or two, the rodents are sacrificed and scientists count up the tumors the animals accumulated in various organs. Most of the rodents in the control group, fed a normal diet, will have tumors anyway because they have been bred to be cancer prone. So, if the test group of rodents fed—or more likely injected with—some chemical at the highest dose has an average of, say, four tumors per animal in a particular organ, and the control group has an average of only one tumor per animal, then the chemical being tested is said to increase cancer incidence by 300 percent (statistical significance is factored in). This does not mean that such a study proves a chemical will cause adverse effects in rats, let alone in humans exposed under more realistic conditions. Yet, this finding, designed as a first step in testing a hypothesis, often ends up in a headline or in a media release from one advocacy group or another attempting to use preliminary research to support a cause or movement.

(6) Next, and often under pressure from the energized media and environmental NGOs, a political body, such as the European Parliament or the U.S. Congress, or a regulatory body, such as the EPA, will classify and/or confirm this chemical as a likely human carcinogen, as if rodents were nothing more than miniature humans.

(7) These agencies then establish an “acceptable” level of the chemical—the EPA calls it “an upper estimate of the risk”—using what's known as the “dose-response curve,” which includes a large margin-of-safety factor based on mathematical models. In moving to this new quantitative

approach, government scientists began employing high-dose rodent studies and the same basic assumptions implicit in the Delaney clause: equating these studies to estimates of what might happen to humans exposed to the same chemicals at low doses. But there are no validated biological models that quantify the relationship between the high-dose animal results and low exposure levels experienced by humans.

Underscoring the relative arbitrariness of this process, the cutoff level is set differently by different agencies from country to country and even sometimes within a country. As in the case of the pesticide atrazine, these levels can vary by as much as 100 times. (The European safety cutoff level is 1 part per billion, while the World Health Organization sets it at 100 ppb.)

The result is that the scientific convention of setting one number to represent risk exaggerates the media and public perception of risk. Because only one number results from the assessment process, it is not surprising that, ignoring cautionary guidance by regulators, NGOs and the media select the country or agency with the tightest cutoff and then portrays this number as exact, as the best estimate of risk and as predictive of cancer incidence. But that misstates what a cutoff number means. As the EPA notes, “The actual risk [from exposure to a chemical] may be significantly lower and may indeed actually be zero. It is important to recognize that the use of this model results in risk estimates that are protective, but not predictive of cancer incidence.” (EPA 1994)

Employing this model, a range of chemicals, including aminotriazole, DDT, cyclamates and Alar, at one time or another, have been in the crosshairs of environmental groups because of

supposed cancer-causing effects on humans. Toxicology studies are important in public health because epidemiology is not very sensitive, as you cannot conduct experiments on humans. They serve as a basis for potency estimates and offer the opportunity to compare risks. However, the advantages of these studies must be balanced with their potential to exaggerate risk. High-dose effects do not necessarily occur at low doses and effects that occur in test species do not necessarily occur in humans exposed to the same agents.

Non-Carcinogenic Risk

In recent decades, there have been numerous claims linking chemical exposures to a wide variety of illnesses besides cancer: asthma, autism, attention deficit disorder, congenital malformations, sperm quality and quantity decline, diabetes, heart disease, Parkinson's and dementia, among others (Safer Chemicals, Healthy Families 2010). To evaluate risks from chemicals that might cause effects other than cancer, the EPA has developed an evaluation model based on the general approach established by the Ames test. It assumes the direct applicability of high-dose laboratory animal tests to humans with subjective additional safety factors built in. The EPA then determines at what level a chemical causes an adverse reaction in the animal most sensitive to that chemical when it is fed the chemical over the course of set period of time. The "safe" human exposure limit is set 100 times (or more; California's Proposition 65 uses 1,000 times) below the highest dose that is not expected to cause an adverse reaction if continuously exposed to a certain chemical. When the data are incomplete, regulators factor in the additional uncertainty by multiplying the safety factor, usually by 10 or even more, bringing the safety margin, or margin of exposure, to 1,000 or more (10,000 times in the case of Proposition 65 listed chemicals; European regulators discuss a margin of exposure of 10,000 as sufficient for protection against

“severe effects”, even carcinogenicity). So, for example, the safe level for adults would be set at 100 times lower than what has shown to adversely impact the most sensitive laboratory animal effected by that substance, while for children or pregnant women the safe dose level would be set 1,000 times or even 10,000 times lower to account for individual differences in humans.

The EPA calls this the Reference Dose (RfD). The term was originally known as the Acceptable Daily Intake (ADI), but it was criticized as potentially misleading as it wasn't clear who was judging acceptability. Today, the meanings of RfD and ADI are synonymous. The RfD is the amount of a substance that a person at a specific weight can take orally every day over a lifetime without any appreciable health risk (with the exaggerated margin-of-error built in) (Barnes and Dourson 1988). Clearly, neither the RfD nor the ADI identifies the amount of exposure that is known to cause adverse effects. It's an outer limit that assumes a lifetime of high-level exposure and is calculated by dividing no-effect doses from animal studies by 100, 1,000, 10,000 or more. These levels are protective in the extreme. But as with cancer exposure levels, advocacy groups and the media often use these safe dose figures as if they are precise levels that when exceeded by even the tiniest amount present a health danger.

Endocrine Disruptors

As toxicological research has become more refined, there has been an increasing focus on the effects of chemicals and drugs on human reproduction, pregnant women, infants and children. Our hormonal systems are acutely sensitive to change. This heightened concern traces back to the thalidomide tragedy in 1961, which was followed a decade later by the diethylstilbestrol (DES) debacle. From about 1940 to 1970, the synthetic nonsteroidal estrogen DES was given to pregnant women under the belief it could treat pregnancy complications and losses. The FDA

subsequently withdrew DES from use in pregnant women when it was shown to cause malformed uteruses and rare vaginal tumors in females who had been exposed to this drug in utero (Herbst, Ulfelder and Poskanzer 1971).

Although these were only two drugs among many thousands on the market, the seriousness of these problems fed a belief that the pharmaceutical industry could not be trusted and the government was lax in its screening of drugs and chemicals and was not adequately exercising its regulatory authority. Unrealistic expectations that drugs (and all chemicals) should be risk-free have occasionally led to beneficial drugs being hastily removed from the marketplace. When reports circulate that someone, somewhere, has had an adverse reaction, there are reflexive calls for a ban and class action attorneys join the fray.

That's what happened in the case of Bendectin, a popular drug prescribed to treat nausea and vomiting during pregnancy. In 1983, an Australian researcher linked it to a variety of disorders, including fetal malformation. The release of the initial study touched off a media frenzy and demands by NGOs that the government withdraw the drug. Lawsuits mounted. Throughout the crisis the drug remained legal under the trade name Dialectin in Canada and Europe, which stood by studies that had found the drug safe. But the beleaguered manufacturer believed it had no choice but to pull it off the U.S. market. Soon after it discovered that William McBride, the scientist who claimed to have found teratogenic effects (which could alter the development of the embryo or fetus) from using the drug, had falsified his research. The FDA subsequently found no links to birth defects and no cause for alarm (Kutcher, et al. 2003) (Willhite and Mirkes 2005). Because of the negative publicity, however, the drug was not reintroduced in the United States.

During the 1990s, based on studies of fish and rodents, some university researchers began focusing on the potential impact of chemicals that appeared in laboratory tests to mimic or impede the effects of endogenous hormones such as estrogen. That's not in itself a cause for concern. Clover, some fruits, wheat and other flour and soy products (including fungal products at trace levels in wheat and other grains that are processed into bread, cereal pizza and even beer) can also potentially alter the way the hormones in our endocrine system work. The natural chemicals that caused this effect were known objectively and innocuously as endocrine mediators.

By the early 1990s, some environmental activists and scientists began promoting a novel hypothesis low doses of certain chemicals might have a more severe impact than high doses. They argued that the reproductive system of animals, including humans, might not be subject to the classic dose response curve; there could be a non-monotonic response (Richter 2007). Looking to distinguish the similar hormonal effects caused by synthetic chemicals, they coined the term "endocrine disruptors," and the label stuck. The term was chosen as a branding slogan, not unlike campaigners on abortion issues labeling themselves "prochoice" or "prolife." Who would want to risk "disrupting" the development of a newborn? The novel notion was promoted in the bestselling book, *Our Stolen Future: Are We Threatening Our Fertility, Intelligence and Survival?* (Colburn, Dumanoski and Meyers 1996). The media and some scientists now use "endocrine disruption" interchangeably with the objective description "reproductive hazard" even though it carries strong normative associations.

While some scientists believe there is persuasive evidence that certain common chemicals, such as the plastic additive BPA, can adversely impact human development, others believe endocrine

disruption remains a hypothesis in search of data after more than fifteen years of research (Sharpe 2010). The use of this novel paradigm has opened a new front against chemicals. Substances that have not been proven to be carcinogenic in humans at common levels of exposure—the pesticides DDT/DDE and dieldrin, dioxin, PCB, PBDE, and PFOA, for example—are now labeled potential endocrine disruptors even though the hypothesis itself remains in question (Kamrin, *The Low-Dose Hypothesis: Validity and Implications for Human Risk* 2007) (Kamrin, *Bisphenol A: A Scientific Evaluation* 2004).

The media and certain NGOs now carelessly link various substances to everything from human breast cancer to early puberty based on animal tests or trace levels found in the environment or in human blood and urine. No longer is it necessary for critics of chemicals to find evidence of actual harm; it is now sufficient to identify metabolic changes in laboratory animals in small-scale hypothesis-driven studies to justify extensive and expensive new tests, which sometimes lead to onerous regulations. The federal government and chemical manufacturers are often portrayed as colluding to protect industry profits at the cost of human health.

Green Chemicals—Natural v. Synthetic

Many people who express concern about chemicals hold the mistaken belief that there are equivalent naturally occurring substitutes that are safer and as effective. Environmental groups have incorporated this argument in campaigns to ban various chemicals, proposing organic or “natural” substitutes. But little publicity is given to the limited effectiveness of many natural substances or the fact that many natural chemicals can also cause “endocrine disruption” or cancer in farm and laboratory animals.

Organic farming advocates maintain that so-called natural farming techniques result in more

nutritious crops. There is no scientific research supporting that belief. The Agriculture Department pointedly “makes no claims that organically produced food is safer or more nutritious than conventionally produced food.” Scientists who systematically reviewed research over 50 years conclude that organically produced foods, including crops and livestock, are not more nutritious than those produced conventionally. (Dangour, et al. 2010) (Rosen 2010) Not using herbicides or pesticides can, in some situations, result in increased stress on plants. If threatened by weeds, insects or poor weather, a plant’s inborn response is to generate protective natural chemicals, including mycotoxins, which can be quite toxic, and potent carcinogens.

Scientists have vigorously attempted to develop effective green chemicals—natural alternatives to synthetics known as biopesticides that can maintain the high yields and low prices upon so critical for mass food production. They have spent years researching the insecticidal properties of rosemary, thyme, clove and mint. According to Murray Isman, a leading researcher in this area from the University of British Columbia, herb-based pesticides have a broad range of action against bugs or weeds, in some cases killing them outright. But Isman says that claims that natural pesticides can replace synthetic chemicals are wildly exaggerated. Because the essential oils made from these herbs tend to evaporate quickly and degrade rapidly in sunlight, farmers need to apply them to crops more frequently than conventional pesticides—some persist for only a few hours, compared to days or even months—making the process labor intensive and expensive. As they are generally less potent than conventional pesticides, they must be applied in higher concentrations to achieve acceptable levels of pest control.

For example, environmental scientists looking at compounds used to combat soybean aphids, a major destroyer of that crop, discovered that “the organic products were much less effective than

... conventional pesticides at killing the aphids and they have a potentially higher environmental impact” (Bahlai, et al. 2010). Some biopesticides, such as the fungicide sulfur, may be more toxic or harmful than their synthetic counterparts. Natural pesticides also may be less selective in what they can kill while synthetic pesticides are developed to destroy only targeted pests. In sum, conventional pesticides remain the most effective and efficient way to control caterpillars, grasshoppers, beetles and other insects the feast on food crops (BBC 2009).

Because plants (unlike synthetic pesticides) don't need to be lab-tested in order to be sold, there's never been much economic incentive to analyze plants for carcinogenicity. It's almost understandable that a romantic view has developed that plants and organic production are naturally safer. Unfortunately, it's not true. So great is humanity's ability to shield itself from most natural threats and so powerful is the spiritual call of nature that we tend to forget that nature can be dangerous. The poisonous plants used as herbicides in organic farming didn't evolve that way out of perversity. By the logic of Darwinian evolution, repelling something that can kill is a good way to live longer and pass on your seeds—especially if you're a plant and can't flee your enemies. Plants have been producing their own pesticides for hundreds of millions of years. Some biopesticides can present unique hazards. They are known as “microbial pesticides,” meaning that the pesticidal material is a fungus, or a virus or a bacterium, often with potential ill effects on humans (Muhawi 2004).

As a result of attempts to promote the belief that any trace of a chemical that can cause cancer in animals should be prohibited for human consumption, people cringe at the thought that produce might have some residues or that chemicals can be found in our blood and urine. Ironically, one of the original proponents of those scary characterizations was Bruce Ames, when he was a

young scientist in the 1960s. After the development of his test in the 1960s, Ames became a favorite of environmental groups, who recruited him to help in campaigns to ban pesticides and herbicides. In later years, in part because of the discovery that many natural substances thought to be harmless were also mutagenic, he reversed his original position and now campaigns against chemophobia. Today Ames is known for his efforts to educate those who reflexively believe that anything natural must automatically be safer than anything synthetic.

As bioanalysis grew in sophistication, Ames turned his sights toward the natural world. He identified 52 natural pesticides, and evaluated them the same way artificial pesticides are tested, using high-dose rodent studies. Of the 52 natural pesticides, 27 caused cancer. The 52 pesticides Ames studied are only a fraction of all natural pesticides, and most plants contain a variety of pesticides. As Ames wrote in a letter to *Science* after the Alar apple incident, “[I]t is probable that almost every fruit and vegetable in the supermarket contains natural plant pesticides that are rodent carcinogens”—and could be subject to a ban under the Delaney clause.³ He developed a relative index of toxicity that expresses the human potency of a carcinogen as a percentage of its potency to laboratory rats and mice. Using this index, the hazard from Alar in a daily lifetime glass of apple juice came to 0.0017%. In comparison, the possible hazard from natural hydrazines from consuming one mushroom a day was 0.1%, and that from aflatoxin in a daily peanut butter sandwich was 0.03% (Ames and Gold 1989).

The public’s top concerns around eating are typically food poisoning, BPA, BSE (bovine spongiform encephalopathy or “mad cow” disease), growth hormones used in animals, animal

³ Alar was used in apple production as a growth regulator. The Natural Resources Defense Council, an environmental group, helped stir public concern in 1989 that led to the withdraw of the chemical. See p. 44.

feed, genetically modified (GM) food—and pesticides. But in today's typical American diet, 99.99 percent of ingested chemicals (by weight) are natural. The average American eats 1 1/2 grams of natural pesticides a day—about 10,000 times more than the amount of artificial pesticides consumed. For example, roasted coffee contains 826 volatile chemicals. (Roasting causes the formation of new chemical compounds.) Twenty-one of those coffee chemicals have been tested on rodents, and 16 cause cancer. A cup of coffee includes 10 milligrams of carcinogens. Among the foods highest in natural pesticides are cabbage, broccoli, collard greens, Brussels sprouts, brown mustard (extremely high), black pepper (very high), nutmeg, jasmine tea, rosemary and apples (without Alar).

Some natural crops contain more pesticides than ones treated with synthetics. All potatoes naturally contain solanine to protect them against blight. Solanine is a fat-soluble toxin that in high concentrations can cause hallucinations, paralysis, jaundice and death. Conventional supermarket celery contains 800 parts per billion of the natural chemical psoralen. Created naturally when the celery is stressed, in high doses it's a poison that can damage DNA and tissue as well as cause extreme sensitivity to the sunlight in humans. Organic celery, grown without the aid of artificial pesticides, can contain as much as 6,200 ppb psoralens—nearly eight times as much as celery harvested conventionally (Moalem and Prince 2007). Farm workers who handle large quantities of the organic celery develop skin rashes and burns. By any rational standard of risk assessment, supermarket celery is safer to harvest and eat than the organic alternative.

Does all this mean that we should give up organic celery or conventional apples or abandon a vegetarian diet altogether because we are exposed to high doses of natural pesticides? Not at all. The chemopreventive effects of the chemicals found in foods outweigh the carcinogenic impact

of the natural pesticides. But it's also true, as Ames has written, "the carcinogenic hazards from current levels of pesticide residue or water pollution are likely to be minimal relative to the background levels of natural substances. ... My own estimate for the number of cases of cancer or birth defects caused by man-made pesticide residues in food or water pollution—usually at levels hundreds of thousands or millions of times below that given to rats or mice—is close to zero." (Ames and Gold 1989)

The cancer and chemical concerns ignited by Rachel Carson and Paul Ehrlich and perpetuated by some NGOs were definitively addressed in a 1996 report from the National Academy of Sciences, *Carcinogens and Anticarcinogens in the Human Diet* (National Academies Press 1996). The NAS concluded that levels of both synthetic and natural carcinogens are "so low that they are unlikely to pose an appreciable cancer risk." Anticipating the debate over the relative merits of green chemicals, the NAS found more danger in organics: "Natural components of the diet may prove to be of greater concern than synthetic components with respect to cancer risk," the scientists wrote.

If pesticides are banned after being said to be dangerous using high-dose rodent exposure studies, we are almost certainly trading a miniscule risk (cancer from artificial pesticide residues) for a more certain one. As well-tested artificial pesticides are phased out, there will be greater crop losses caused by insects, wholesome fruit and vegetables will become more expensive, and some people will not be able to afford to eat them as often and will substitute carbohydrates. Overall health will suffer and some people in fact will develop serious complications from obesity, including diabetes. There is no such thing as a risk-free world. Every choice is a trade-off of one risk for another. Assessing environmental risk, particularly in our food supply, will

remain a major challenge going forward (Krewski, et al. 2009). Toxicity testing and risk extrapolation remain arts as well as science.

POLITICS OF THE PRECAUTIONARY PRINCIPLE

Growing out of the environmental and Green movements in Sweden and Germany in the 1960s and '70s, the precautionary principle has become a key environmental regulatory standard in Europe and Canada. Although scientific advisory panels often resist applying the principle, its influence is growing year by year. It has flourished in international policy statements, conventions dealing with high-stakes environmental concerns in which the science is uncertain, and national strategies for sustainable development. Instead of acting against environmental risks after they have been assessed, it suggests that it is more appropriate to take regulatory action when there is only the hint of danger. It's a hazard standard, one that is gradually replacing the risk standard still used (but under assault) in the United States and in most of the rest of the world when it comes to chemical regulation.

The primary foundation of the precautionary principle and the basis for many globally accepted definitions emerged out of the work of the Rio Conference, or "Earth Summit," in 1992.

Principle No. 15 of the Rio Declaration notes:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (United Nations Environment Programme 1992).

Subsequently, a group of activists, the Science and Environmental Health Network (SEHN), met in 1998 at what was known as the Wingspread Conference to further lower

the threshold from “threats of serious or irreversible damage” to “threats of harm.” As in the UNEP definition, and subsequently as it’s used today, lack of scientific evidence or certainty cannot be cited to block its invocation:

When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically (Science and Environmental Health Network 1998).

In its crudest application the precautionary principle has been invoked as a means of deciding whether to allow corporate activity and technological innovation that *might* have undesirable side effects on human health or the environment. In practice, the principle is strongly biased against the process of trial-and-error so vital to progress and the continued survival and wellbeing of humanity.

The notion is difficult to define, which presents challenges to regulators. It loosely suggests that if any human activity raises a perceived threat of harm, sanctions can be imposed even if no cause-effect relationship can be established scientifically. Some substances are held to be intrinsically dangerous at any level, even absent definitive risk data. It assumes as its formulative basis that concern over worst-case scenarios should drive regulation. Simply the possibility of a problem could be enough to justify its use. In its most extreme application, no trade-offs can be considered, such as whether the economic costs of regulation outweigh the potential benefits of reducing far-fetched risk or marginal health or safety improvements.

Supporters of the principle view it as a necessary tool of risk management. While well intended

by many of its proponents, it inherently biases decision-making institutions toward the status quo. Critics also see it as an amorphous concept that lends itself to a reactive, excessively pessimistic view of technological progress and empirically based risk analysis. Applied cynically, it can be used as a thinly veiled tool to legitimize trade barriers under the cover of public policy. Indeed, over the past 10 years, the European Union has increasingly used the standard to support a variety of import bans—ranging from hormones in beef and milk, to aflatoxin in peanuts, to genetically engineered crops—leading to accusations of protectionism from the U.S. and other trade blocs. While it can be applied in areas as different as climate change and anti-trust policy, a primary focus has been consumer products and food and the modern technologies used to produce them.

The move towards precautionary regulation accelerated in Europe in the 1990s because of a series of health scares, which contributed to the belief that traditional risk analysis methods and environmental policies had failed to adequately protect the public. Institutions, governments, politicians and scientists in Europe were eager to regain the public trust lost after outbreaks of BES in the United Kingdom and elsewhere, dioxins in Belgium and HIV-contaminated blood transfusions in France.

The precautionary principle has been the basis for that continent's ban on GM foods and many agricultural chemicals—in many cases without supporting data suggesting adverse health consequences in humans. Various shades of it have been integrated into the EU's regulatory system, REACH, which deals with the Registration, Evaluation, Authorization and Restriction of Chemical substances. The new law, entered into force in June 2007, justifies Europe's move away from risk-based calculations in all areas of science.

The EU uses the precautionary principle as a proactive tool of both risk assessment and risk management to be used in situations where science cannot provide definitive answers. In its February 2000 communiqué, the European Commission distinguished a “prudential approach,” declaring:

“... [A]pplication of the Precautionary Principle is part of risk management, when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy” (EU Commission of the European Communities 2000).

By definition, risk assessment now includes a political dimension based on a chosen level of a perceived threat. Although the precautionary principle was not originally established to complement a scientific approach to risk, it has increasingly evolved to become a tool for the advancement of the views of more radical environment and health advocates.

The U.S. regulatory system of chemicals relies primarily on peer-reviewed science and risk assessment using hazard and exposure data and a weight of evidence standard. But precautionary standards are reflected in the FDCA of 1938 and subsequent revisions, including the Delaney clause, as they required some measure of pre-market proof of safety. On an absolute basis, of course, this is scientifically impossible because everything, natural and synthetic, can be shown to be toxic.

As a consequence of this developing worldwide precautionary ethic, caution is now throttling the regulatory engine around the world. Lawmakers often respond to mere suggestions of potential

harm with reckless proposals for bans or restrictions without any cost-benefit analysis or assessment of the unintended risks that such actions might impose on our health and economy. When scientists push back, the gridlock emboldens critics and heightens consumer anxiety both about the exaggerated dangers of what are often relatively harmless substances and the government's apparent lack of ability to regulate these "harmful" chemicals. This standoff has become even more pronounced in recent years with the high-profile campaigns against phthalates, BPA and atrazine.

Even consumer labels and "green guides," when misused, can undermine confidence in government oversight and demonize chemicals that have been tested and approved as safe. Advocacy groups promote these guides as a way to help the consumer through the thicket of dangerous chemicals, when in truth they often inflame an irrational fear that synthetic substances are more harmful than natural ones. "A rose may be a rose. But that rose-like fragrance in your perfume may be something else entirely, concocted from any number of the fragrance industry's 3,100 stock chemical ingredients, the blend of which is almost always kept hidden from the consumer," writes the Environmental Working Group in an online diatribe against the cosmetic industry (Environmental Working Group 2010). It writes that perfumes often contain what it calls "secret chemicals" not listed on labels that can trigger severe allergic reactions, cause cancer, impair neurological development or disrupt hormones, even at the minute levels these mystery chemicals are supposedly found in cosmetics. EWG provides no documentation for such exaggerated claims.

EWG, EDF and other NGOs propose labeling approved ingredients based on how rodents are impacted when exposed at dosage levels a thousand or more times higher than what might be

experienced by humans. So, for example, harmless perfumes made by Calvin Klein, Jennifer Lopez, Victoria's Secret and other brands would be labeled as carcinogens or endocrine disruptors or neurotoxins (Environmental Working Group 2010). Such an addition, of course, would be equivalent to adding a skull-and-crossbones to the label, dooming a perfectly safe product and throwing a cloud over an entire industry. Yet this EWG report was approvingly disseminated through cyberspace and credulously featured by the mainstream media.

Environmental NGOs and the Media

The rise of the environmental movement and the fragmentation of the media in the age of the Web have led to a growing influence of advocacy organizations with the power to amplify almost any argument. Google has become the ultimate megaphone. Even the most discredited narrative can get a toehold in cyberspace, winding its way back into mainstream discourse and assuming a legitimacy that would have long-since disappeared in a more critical, linear age.

Many advocacy NGOs have become masters at this kind of information manipulation. They've capitalized on the erosion of trust in authority, raising their profile to play an outsized role in the national debate over our environmental future. Among the most adept and well funded are EDF, the NRDC, Greenpeace, National Wildlife Federation (NWF), Center for Science in the Public Interest (CSPI), Union of Concerned Scientists (UCS) and, more recently, EWG. They've also exploited advanced analytical techniques that measure very small levels of a chemical not only in the environment, but also in human tissues and fluids. NGOs now regularly provide their own interpretations of government studies, publicizing what they claim are understatement of danger (Environmental Working Group 2005) (Environmental Working Group 2010).

When chemical traces are found in our blood or urine, at whatever level, the narrative presented

by interest groups is often one-sided. For example, advanced technological analyses of water samples have been used to show the presence of miniscule amounts of drugs or agricultural chemicals at levels far below what scientists believe can cause an effect on the most sensitive animals—with an additional 100-fold or 1,000-fold level of safety built in. That’s why scientists conclude that these chemicals as normally encountered in the environment are not harmful—the exposure levels are just too low to be meaningful (Centers for Disease Control and Prevention 2010). Unfortunately, articles that demonize chemicals often prompt citizens and politicians to act hastily on the belief that the presence of a chemical at any level leads inexorably to an adverse health effect.

The NRDC campaign against Alar in 1989 is the paradigmatic example of how a NGO helped rewrite the narrative on a chemical once considered relatively innocuous. The NRDC worked with CBS’s *60 Minutes* to promote its report on the dangers of Alar (the trade name for daminozide), a chemical sprayed on apples to regulate their growth and enhance their color. The February 1989 broadcast, largely based on the NRDC report “Intolerable Risk: Pesticides in Our Children’s Food” told an audience of some 40 million people that Alar was a dangerous carcinogen. Then NRDC’s public relations firm, Fenton Communications, which has since become a giant in the PR industry by working with environmental campaigners, lobbied other major news organizations to feature the story.

David Fenton, the PR company’s founder, struck gold when he got Meryl Streep, then one of Hollywood’s hottest actresses, to front the story, even though she had no special knowledge of apples or Alar. Fenton teamed up with a long-time friend, David Gelber, a producer at *60 Minutes*, which aired a devastating feature. Streep subsequently testified before Congress and

toured TV talk shows. Not surprisingly, the public panicked and CBS saw its ratings shoot through the roof. School systems removed apples from their cafeterias, supermarkets took them off their shelves and orchard owners lost millions of dollars (Rosen 1990).

Backed into a corner by the controversy, the manufacturer pulled Alar from the market after the EPA wrote in a release, “[L]ong-term exposure to Alar poses unacceptable risks to public health,” although the government cited no specific study. The high-dose research on which the EPA apparently based its hasty comments indicated that the only chance of human poisoning would come if a person ate thousands of apples a day for years. Since the infamous scare, virtually every reputable scientific body and leading scientist, including the National Cancer Institute, the American Medical Association, the World Health Organization (WHO), and the U.S. surgeon general have gone on record as saying that the use of Alar on apples never posed any serious risk.

The manufacturer’s decision to withdraw Alar validated what is now the standard NGO campaign model: create scares (often working hand-in-glove with activist public relations agencies, such as Fenton, and compliant journalists, such as those at *60 Minutes*) to put industry on the defensive and embarrass government officials into making rash decisions based on public opinion rather than science. That cynical cycle has only exacerbated public mistrust of both industry and government.

Reforming the Toxic Substances Control Act

Considering the tenor of the public discourse about chemicals, it is understandable why there is increasing public concern about potential risks in our food, air, water, soil and consumer products. The major anxiety by industry—and indeed by many scientists around the world—is

that the weight of evidence deliberations that are the basis for most U.S. regulations will be usurped by politics. Environmental NGOs are targeting the 1976 Toxic Substances Control Act (EPA 2010), which they hope to evolve into the country's central chemical oversight legislation.

Concern that developing embryos, infants and children are more sensitive to chemicals than adults led to the passage of the Food Quality Protection Act (FQPA) of 1996 (U.S. Congress 1996). Under the statute, the EPA was required to evaluate chemicals at a stricter level than TSCA, defining safety as a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." Costs and benefits could be a consideration for nonfood pesticide uses, but for food use only public health could be considered. In 1998, the EPA aggressively revised its approach to include an additional 10-fold safety factor for children (EPA 1998).

The latest battle over TSCA revolves around whether the U.S. will continue to embrace a risk-based view of chemicals (but modernized to reflect scientific data on non-carcinogenic effects) or a precautionary model grounded in fear of unknown or suspected hazards. Under the act, manufacturers must inform the EPA of their intent to manufacture a new chemical and present evidence about its risks and potential benefits. Regulators must weigh the costs of restrictions against the economic benefits of keeping the chemical in commerce. The act does not require assessment of the safety of thousands of chemicals previously evaluated and "grandfathered in" when the law was passed; nor does it apply to substances regulated under other legal frameworks, such as the FDCA or the Federal Insecticide, Fungicide and Rodenticide Act.

Other than screening new chemicals and regulating the five designated ones, the execution of

TSCA's mandate is vague, partially because Congress failed to define what constitutes a reasonable risk of injury and how to evaluate that risk. One prominent critic, Andy Igrejas, environmental-health campaign director for the Pew Charitable Trusts, maintains that the U.S. "has no real program to regulate industrial chemicals," as a result of TSCA's "deep flaws" (Case, *The Real Story Behind Bisphenol A* 2009). There is pressure from environmental advocates to extend to TSCA provisions of the Delaney clause that now exist for synthetic food additives to other chemicals, such as bisphenol A (even though BPA is not believed to be carcinogenic in humans). According to the Delaney clause, if a synthetic food additive causes cancer in test animals at any dose it must be prohibited. If more widely adopted that would amount to a problematic precautionary test; people are not typically exposed to the high doses given to laboratory rodents and if the animals get cancer that does not guarantee that humans exposed to lower doses will suffer the same fate.

EPA administrator Lisa Jackson announced that reform of TSCA was high on her list of priorities when she assumed her position in January 2009. Senator Frank Lautenberg, Democrat of New Jersey, has proposed overhauling the whole system of regulating chemicals with the introduction of the Kid-Safe Chemical Act, which would require manufacturers to demonstrate their safety in order to introduce new chemicals or keep current ones on the market (U.S. Congress 2009). A House draft version of the bill would require the EPA to maintain a list of 300 priority chemicals to investigate "based on available scientific evidence, consideration of their risk relative to other chemical substances and mixtures, presence in biological and environmental media, use, production volume, toxicity, persistence, bioaccumulation, or other properties indicating risk."

It's unclear from the draft bill what criteria would be used to designate a chemical as "dangerous." The recommendations are a hodge-podge, a mix of politics and precautionary-based notions. For example, in the proposed legislation, the non-carcinogenic BPA, found safe by all pertinent U.S. agencies and foreign scientific advisory boards, is grouped in the same category as lead, asbestos, cadmium and other known carcinogens (Willhite, Ball and McLellan 2008). The major concern is that the public bias against "all things chemical" will be incorporated in ill-conceived legislation that could undermine the long-standing regulatory commitment that relies on "best available data."

President's Cancer Panel Annual Report for 2008-2009

These contradictions were borne out in the 2008-2009 report by the President's Cancer Panel, a three-person committee that advises the White House each year on national cancer strategy (National Cancer Institute 2010). It's a jarring insight into just how endemic this new iteration of chemophobia has become in our society.

Nearly 1.5 million new cases of cancer are expected to be diagnosed each year; 562,000 Americans will die from the disease. Approximately 41 percent of people in the U.S. will be diagnosed with cancer at some point in their lives. The societal costs are staggering: an estimated \$243 billion each year. The Executive Summary reads as if exposure to exogenous chemicals were the primary cause of these cancers. The report is entirely devoted to environmental factors. It claims the proportion of cancer cases triggered by chemicals in the environment has been "grossly underestimated," warning of "grievous harm" from chemicals and other hazards and "a growing body of evidence linking environmental exposures to cancer."

The report was scathingly and bewilderingly received by many cancer and chemical experts. The

panel failed to invite scientists from the FDA, EPA, NAS, NIOSH, OSHA or the National Toxicology Program (NTP) to comment on environmental chemical risk, which raised doubts about the report's independence and scientific credibility. In an analysis entitled "Cancer Report Energizes Activists, Not Policy," Reuters' Health and Science editor noted, "[T]he report from the President's Cancer Panel ... has underwhelmed most mainstream cancer experts and drawn only a puzzled response from the White House. Even members of Congress who usually are eager to show they are fighting to protect the public have been mostly silent. Cancer experts say for the most part that we already know what causes most cases of cancer and it's not pollution or chemicals lurking in our water bottles" (Fox 2010).

Michael Thun, an epidemiologist from the American Cancer Society, wrote in an online response that the report was "unbalanced by its implication" and had presented an unproven theory on environmentally induced cancers as if it were a fact. Suggesting that the risk is much higher when there is no proof diverts attention from things that are much bigger causes of cancer, like smoking, Dr. Thun said.

The consensus among cancer experts is that tobacco and diet (obesity) are the leading causes of cancer, together making up half to two thirds of all cases. Infections are believed to cause 15-20 percent of the cancers with radiation, stress, lack of physical activity and environmental pollutants causing the rest. "Maybe up to 4 percent of cancer in the Western world is caused by contaminants and pollution and yet we are chasing new, unknown causes rather than focusing on acting on what we know," said Graham Colditz, an epidemiologist at the Washington University School of Medicine in St. Louis and an adjunct professor at the Harvard School of Public Health. "Things like this report are making it harder to move the nation to a healthier lifestyle."

The report does acknowledge that there is no hard evidence that environmental factors play a significant role in causing cancer—200 pages in. After sensational speculation about the potential dangers of certain chemicals the report concedes, “At this time we do not know how much environmental exposures influence cancer risk.” The dearth of evidence did not stop the authors from proposing that the government actively restrict chemicals based on consumer concerns, even absent evidence of actual harm and despite the costs of such regulation.

CASE STUDY: BISPHENOL A—PRECAUTIONARY REGULATION

The President's Cancer Panel report contains numerous overstatements and inaccuracies, which reflect the panel's reliance on the perspective of advocates and select scientists rather than a broad representation of scientists most familiar with studies on the chemicals commented upon. One primary target about which the panel gets considerable information wrong is bisphenol A, an industrial chemical used to add strength and flexibility to many plastics and to make the epoxy resins that are used to line canned goods to prevent contamination. In the opening letter to the president, the panel notes, "bisphenol A (BPA) is still found in many consumer products and remains unregulated in the United States, despite the growing link between BPA and several diseases, including various cancers." The panelists urge the government to take precautionary measures to restrict its usage.

The controversy surrounding bisphenol A dramatically illustrates the virulence of chemophobia and the new forms it is taking. BPA is one of the most ubiquitous chemicals in the world. It has been in use for more than 50 years in the manufacture of polycarbonate plastics and epoxy resins in dentistry; in thermal paper production; and as a polymerization inhibitor in the formation of some polyvinyl chloride plastics. It is found in electronics, DVDs, car dashboards, eyeglass lenses, and microwavable plastic containers. Approximately 6 billion pounds are produced globally each year. When used as a building block in polycarbonate plastic products, BPA makes them stronger—hard enough to replace steel and transparent enough to substitute for glass. Polycarbonate can withstand high heat and has high electrical resistance. At present, alternatives for many of its uses—such as in the protective coating of metal can liners, where it does not

affect taste, helps prevent bacterial contamination and extends shelf life at a relatively low cost—do not exist for most foods (Layton 2010).

Campaigns Against BPA

BPA is also one of the world's most studied chemicals—it has been subject to literally thousands of studies. In 1982, the National Cancer Institute and the National Toxicology Program cleared it as a potential carcinogen (National Toxicology Program 1982) and a review by the EPA endorsed its safety in 1988 (EPA 1988). Twenty years later, in 2008, the FDA reviewed the studies to date and declared BPA safe at estimated levels of human exposure (U.S. Food and Drug Administration 2008). A year later, in 2009, under pressure from advocacy groups that had sharply criticized the findings as an example of the Bush administration's alleged anti-science bias, the Obama Administration announced the FDA would reassess the 2008 review.

For the past four years, BPA has been under constant attack by select environmental groups, journalists and some social scientists campaigning to ban the chemical outright or restrict its use in products handled by infants and children (Case, *The Real Story Behind Bisphenol A* 2009) (Vogel 2009). The point organization for much of this criticism is EWG, which has been actively lobbying for a ban since 2007. EWG is most noted for its work lobbying for a ban of phthalates. EWG does not have any scientists with targeted expertise in plastics. That does not deter it from regularly seeding the Web with sensational, simplistic and often-misleading interpretations of complex studies. For example, in November 2009, as the environmental community anxiously awaited the FDA's decision regarding BPA, EWG posted a report on the *Huffington Post* with the headline, "BPA Wrecks Sex, Fouls Food—and Probably Worse" (Shannon 2009).

The public campaign conducted by EWG and other advocacy organizations has led to thousands of stories by mainstream news organizations and on the web. The *Milwaukee Journal Sentinel* alone has published no fewer than 50 stories—for which it has won a bushel of journalism awards—excoriating the government for not restricting or banning the use of BPA. It consistently frames the issue using what can only be characterized as sensational tactics. In what it calls a “Watchdog Report,” the *Journal Sentinel* warned that BPA could cause, in humans, “cancers of the breast, brain and testicles; lowered sperm counts, early puberty and other reproductive system defects; diabetes; attention deficit disorder, asthma and autism” (Milwaukee Journal Sentinel 2010)—none of which is supported by scientific studies or international regulatory agencies.

A feedback loop has developed among news organizations and select environmental groups and consumer advocates promoting the view that BPA is unsafe. In its December 2009 issue, *Consumer Reports* repeated unfounded allegations that “BPA has been linked to a wide array of health effects including reproductive abnormalities, heightened risk of breast and prostate cancers, diabetes, and heart disease” in humans—erroneous claims that subsequently turned up in the President’s Cancer report but which have been rejected by the NTP, risk assessments by the FDA and the European Union. Rejecting the findings of research authorities, the magazine urged the FDA to revise its “inadequate and out of date” standards. (Consumer Reports 2009) The *Consumer Reports* article inspired panic-inducing reaction stories at ABC News, the *Los Angeles Times*, Fox News and *The New York Times*, as well as hundreds of other articles in smaller publications and on the web. The Susan G. Komen Foundation was so overwhelmed and alarmed by calls from frightened women, it consulted with a top expert in the field, Melissa

Bondy, an epidemiologist at the University of Texas MD Anderson Cancer Center. “[T]here is no evidence to suggest a link between BPA and risk of breast cancer,” Bondy concluded in a summary alert still posted on the foundation’s website (Susan G. Komen for the Cure 2010).

Considering the change in ideological complexion at head of the FDA, ban proponents were taken aback in January 2010 when the agency announced it was standing by its 2008 conclusion that BPA is safe as used. It declared the chemical posed “negligible” or “minimal” concern for most adults and “is not proven to harm children or adults,” concluding, “[s]tudies employing standardized toxicity tests used globally for regulatory decision making thus far have supported the safety of current low levels of human exposure to BPA.” (Food and Drug Administration 2010) When asked directly if adults or children faced any real health dangers, Joshua Sharfstein, M.D., the FDA’s principal deputy commissioner, minced no words: “If we thought it was unsafe, we would be taking strong regulatory action” (National Institutes of Health 2010). While reaffirming there were no dangers, the FDA report recommended ways to limit exposure to BPA and said it is funding more studies.

In its study, released four months after the FDA report, the White House Cancer Panel ignored the FDA’s conclusion that BPA was safe for adults and infants and that families should not change their use of infant formula or food. Instead, the report cited selective and out of context elements of the FDA statement to reinforce the belief that BPA is unsafe. The panelists also claimed—erroneously—that the NTP had said “there is cause for concern” about the chemical’s link with reproductive abnormalities, when the NTP in fact concluded there was “negligible concern” for reproductive effects.

If the FDA had taken action and supported restrictions, it would have come as a shock to regulators worldwide. BPA has undergone comprehensive reviews by 10 other regulatory bodies in Europe, North America, Asia, Australia and New Zealand (Butterworth 2009). In what is considered the most comprehensive and definitive review to date, in 2006, the European Union's European Food Safety Authority (EFSA) certified that BPA is safe for use in products handled by adults and infants (EFSA 2006).

The EFSA took up the issue once again in 2010 after the French and Danish government decided to ban BPA in food-contact products for infants and toddlers based on what they saw as uncertainties raised by a recent report of BPA's neurotoxic effects on rodents, known as the Stump study (Stump, et al. 2010). The EFSA panel of 21 scientists consulted with international risk assessment authorities, including the FDA, Health Canada and the WHO, and conducted a comprehensive review of the Stump study and all research on BPA toxicity through July 2010. On September 30, the EFSA reasserted there is no "convincing evidence" of neurobehavioral toxicity of BPA, concluding, "[T]hese studies have many shortcomings" and are not relevant to human health (EFSA 2010).

Once again, what is most notable is that even though obligated to assess chemical exposures on precautionary grounds, EFSA has continued to find that the low-dose rodent studies are not methodologically or statistically convincing. Its conclusion: BPA is safe as used by adults, infants and pregnant women.

How does it happen that a White House panel of supposed experts glibly endorses regulating BPA in the U.S. as Europe regulates it in the belief that the EU would restrict its use under the

precautionary principle—but is so sloppy in its work that it does not know that European regulators have consistently come to the same conclusion as U.S. regulators, that BPA is harmless? How does it happen that a substance consistently deemed safe by reviewing bodies and scientific studies remains in the crosshairs of campaigning journalists, politicians and environmentalists? What does this controversy suggest about how scientific decisions are made in a highly charged political environment?

Low Dose Theory

Researchers generally agree BPA is neither mutagenic nor a likely human carcinogen (Haighton, et al. 2002). There is disagreement, however, about whether the chemical presents any other danger to children or infants. The controversy results from the newer ways scientists are attempting to evaluate chemical risk. Some scientists and NGOs have zeroed in on evidence that trace levels of BPA can leach from plastic and show a laboratory response on estrogen-responsive cancer cells (Krishnan, et al. 1993). It's been labeled an “endocrine disruptor.” Such a finding is not necessarily, or even likely, a cause for concern. As previously noted, many natural substances that alter the way the hormones in our endocrine system work and are potent, and present at levels comparable to or higher than BPA.

The studies on BPA do indicate serious hormonal effects on rodents when BPA is injected or consumed at levels at least 500,000 times greater than humans consume (Dekant and Völkel 2008) How meaningful are these findings for humans, who are exposed to only the tiniest fraction of the chemical injected into rats?

Chemicals tested on animals rarely have identical effects on humans at comparable dosages, and sometimes have no discernible effect because of inherent flaws in studies and significant

differences between the species in biochemistry, physiology and other metabolic systems. Other doubts have been raised because of what scientists call non-reproducibility—estrogenic effects and reproductive impacts shown in one laboratory cannot be confirmed in others (Kamrin, *Bisphenol A: A Scientific Evaluation* 2004).

It's also important to distinguish whether an experiment on BPA was carried out using oral studies or by injections. The reproducible studies have been almost all been experiments in which BPA has been administered by injection. But humans are not exposed to BPA through injections. In humans, BPA is ingested; 99 percent of exposure is through our diet.

Consequently, regulatory agencies do not put much stock in tests in which a substance is introduced to subjects in a different way from that to which humans are exposed. The European Food Safety Authority, Health Canada, WHO, the FDA, the NTP and every regulatory body that has systematically assessed the risks of BPA either reject studies of injected BPA outright or gives strong preference to those in which animals receive BPA orally. While studies in which rodents were injected with BPA have shown some (but often contradictory) effects, the results from experiments in which rats receive the chemical orally have proved biologically implausible and not reproducible (Howdeshell, et al. 2008).

Why would that be the case? BPA taken orally is rapidly detoxified, first in the gastrointestinal tract and then in the liver (Doerge, et al. 2010). Enzymes transform BPA into a water-soluble chemical known as BPA-glucuronide, which repeated studies have shown is harmless. Within a few hours of being ingested, it's not chemically active and does not accumulate in tissues.

Rapidly excreted in urine, this substance has a half-life of just six hours (Völkel, et al. 2002).

Even when used in dental sealants, BPA exits the system in fewer than 24 hours (Joskow, et al.

2006). Regulators are thus faced with a dilemma. The injection studies on BPA are contradictory and often were not carried out using Good Laboratory Practices (GLP); ingestion studies, when positive, have generally been of questionable quality and not reproducible; and studies on oral ingestion of BPA make it clear that BPA, taken orally, is soon rendered innocuous and excreted.

There is a common, and seemingly damning, allegation against BPA, that turns up repeatedly in media reports and even some academic studies: BPA has been found in the urine of more than 93 percent of people over six years old (Calafat, et al. 2007). That assertion even appears in the President's Cancer report.

That makes for a sensational headline, but what does it mean? Not much. Advanced bioanalysis ensures we can find many chemicals in nanogram levels even in pure water used for high-performance liquid chromatography. To put these findings in perspective, tests by the CDC have also found dietary estrogens (called phytoestrogens)—known hormone “disruptors” that occur naturally in a vast array of products such as nuts, seeds, soy, tofu, wheat, berries, bourbon and beer—in the urine of more than 90 percent of people, with some at levels 100 times higher than traces of BPA. Moreover, the miniscule amount of BPA or dietary estrogens that might somehow be found in urine are considered harmless, as it is pharmacologically inactive and doesn't bioaccumulate. The White House report got it wrong when it stated that the CDC had found biologically active BPA in 93 percent of Americans, when the CDC had actually found that 98 percent was biologically inactive (Centers for Disease Control and Prevention 2010).

Time and again, the CDC has weighed in on this point, only to be ignored by the media. “In animal and human studies, bisphenol A is well absorbed orally,” the CDC notes (citing numerous

studies) in its latest report on BPA, released in July 2010. “Finding a measurable amount of bisphenol A in the urine does not mean that the levels of bisphenol A cause an adverse health effect. ... In humans, little free bisphenol A circulates after oral absorption due to the high degree of glucuronidation by the liver. The glucuronidated bisphenol A is excreted in the urine within 24 hours with no evidence of accumulation.”

The only significant science-based question is whether a particular substance is harmful at the trace levels to which humans are exposed. The debate over BPA has been riddled with distortions over what levels might be toxic. NGOs jumped on a study from China suggesting that Chinese workers who handled BPA in bulk in unsafe conditions had lower sperm counts (Kaiser Permanente Division of Research 2009). The EWG disseminated the story and the *Los Angeles Times*, *Milwaukee Journal Sentinel* and other organizations played it up with outrageous, out-of-context headlines. But the study was extremely preliminary. Only a fraction of the workers at the plant agreed to participate in that study, which did not correct for other confounders, such as whether the workers with low sperm counts smoked (more than 68 percent of the workers at the plant smoked, and smoking is a proximate cause of low sperm count).

Incidents of occupational exposure to BPA are incredibly rare and prior research suggests that workers handling it at high concentrations and without protective equipment may not be in harm's way (Guobing, et al. 2005). Moreover, research on workers exposed to level hundreds or thousands of times higher than consumers might face (even in extreme circumstances) provides no insight as to its potential to harm as the chemical is normally encountered. The NTP has reported “negligible concern” that men exposed at non-occupational capacities—in other words, men who are exposed to BPA from using plastic containers or consuming canned foods—would

experience reproductive effects (Center for the Evaluation of Risks to Human Reproduction 2008).

Ideological Regulation

The scientific community appears divided into two conflicting camps when it comes to assessing BPA's risks. Regulatory authorities and scientists, who rely on long-established study protocols, including GLP, are on one side, and they have concluded, almost unanimously, that BPA presents no serious harm. They represent the majority, but their views are often downplayed or even ridiculed by advocacy groups and a small faction of university-based scientists who embrace precautionary notions and the low dose, endocrine disruptor paradigm. These disputes have turned acrimonious on occasion at academic conferences, where shouting matches have broken out, and in premier journals, where the shouting is in ink. Over the summer, *Nature* published a long "Letter to the Editor" by two distinguished FDA toxicologists taking the journal to task for what they claimed was "biased" reporting for trying to explain away why low-dose BPA studies are yielding contradictory results that regulators consistently find wanting (Lorentzen and Hattan 2010).

One of the major differences between the two approaches is that the studies by university scientists are hypothesis-driven: they are usually small studies asking targeted questions, designed to challenge existing paradigms. Free of regulatory responsibilities, they often trumpet their findings to a general press that is ideologically sympathetic. The majority of the state-of-the-art larger studies—that follow GLP and upon which the FDA and other regulators rely—have shown few consistent effects from BPA. The government sometimes mandates these larger GLP studies, and industry is required to fund them. That presents an easy target for critics,

including activist academics, NGOs and journalists, although there is no evidence that any “industry-funded” data has been manipulated or compromised. In essence, there is a clash of cultures between academic research scientists, who are testing new hypotheses and have serious concerns about the hormonal and epigenetic (i.e. non-genetic factors that cause an organism’s genes to behave or express themselves differently) effects of BPA and regulatory scientists, who must weigh a range of risks and unintended consequences before enacting or changing regulations.

These differences reappear every time a new study comes out. In 2001, the NTP released an independent study of the evidence for and against the novel hypothesis. In its conclusion, the report says, “The Subpanel is not persuaded that a low dose effect of BPA has been conclusively established as a general or reproducible finding,” although it did recommend further review (National Toxicology Program 2001). Numerous studies followed, including one by the Harvard Center for Risk Analysis (Gray, et al. 2004) (Goodman, et al. 2006). All of them raised doubts about the validity of the low-dose hypothesis and the reproducibility of findings based on tests performed on animals injected with BPA. Nevertheless, after each of these studies, the authors were attacked. Frederick S. vom Saal, an expert in animal neurobiology at the University of Missouri who has emerged as the most vocal critic of BPA, argued that these reports all failed to take into account the “latest knowledge” in endocrinology, developmental biology, and estrogen-receptor research (vom Saal and Hughes 2005).

To respond to the consensus of BPA’s comparative safety, in 2006, vom Saal coordinated a conference that brought together dozens of skeptical scientists, 38 of whom signed a statement endorsing the low-dose endocrine-disruptor hypothesis. These committed signees are the

scientists noted by the President's Cancer Panel and many media reports as "independent." Considering the lack of dissenting viewpoints, their summary conclusion, known as the Chapel Hill Consensus Statement, was hardly surprising. It found BPA associated with "organizational changes in the prostate, breast, testis, mammary glands, body size, brain structure and chemistry, and behavior of laboratory animals" (vom Saal, et al. 2007). Using inflammatory language uncharacteristic of science, vom Saal summed up their conclusion: "The science is clear and the findings are not just scary, they are horrific. When you feed a baby out of a clear, hard plastic bottle, it's like giving the baby a birth control pill" (University of Missouri College of Arts and Sciences 2005).

The "consensus" statement was widely disseminated in the worldwide media and led to hearings in many countries, where the debate took on a decidedly ideological edge. Public concerns sparked a review by Health Canada. When Mark Richardson, the chief scientist and head of the study, unofficially concluded the evidence showed that the dangers of BPA were "so low as to be totally inconsequential" and compared its estrogenic effects to tofu, activists and the media, led by *The Globe and Mail* of Toronto, mounted an attack on his credibility that led to his reassignment (Mittelstaedt 2007). Months later, when the official report was finally issued, Health Canada echoed Richardson's findings and rejected claims that BPA was unsafe. "The current research tells us the general public need not be concerned," Health Canada declared after reviewing hundreds of studies. "Bisphenol A does not pose a risk to the general population, including adults, teenagers and children" (Government of Canada 2008)

Nonetheless, the precautionary principle is embodied in the law in Canada (and in the EU, where it is applied differently, but not yet in the U.S.). Considering the anxiety generated and absent

convincing scientific evidence, Canadian officials felt compelled to ban polycarbonate baby bottles (although other infant products containing BPA were deemed safe). “Even though scientific information may be inconclusive,” Health Canada wrote, “decisions have to be made to meet society’s expectations that risks be addressed and living standards maintained.” Activists now regularly and disingenuously (or out of ignorance) cite the Canadian ban, arrived at through fear rather than based on scientific evidence, as “proof” that regulatory bodies are now finding BPA harmful.

The stage then shifted to Europe, which has slightly different precautionary standards. In a stunning turn of events, health authorities in France rejected the opportunity to follow in Canada’s footsteps. “Canadian authorities banned BPA under public pressure and without any serious scientific study,” Minister of Health Roselyne Bachelot said during an inquiry at the National Assembly in March 2009. “The precautionary principle is a principle of reason and under no circumstances a principle of emotion,” she concluded, noting, “It applies when there are no reliable studies. Here, there are reliable studies, which conclude, with current scientific data, that baby bottles containing this chemical compound are innocuous” (Rimondi 2009).

In late spring 2010, after a renewed campaign by activists using the now discredited Stump study, the French Senate and Assembly put aside the scientific findings and the recommendations of its health minister and approved a ban on infant bottles containing BPA. A precautionary ban went also into effect in Denmark in July 2010. Both the French and Danish bans remain in effect even though the study that fed the concerns was dismissed as inadequate and unpersuasive in the latest EFSA review.

FDA and EPA Weigh In

In recent years, the U.S. government has committed tens of millions of dollars, and promises to spend an additional \$30 million under the stimulus bill, in an attempt to resolve remaining questions about the potential danger of BPA. In the government's first major review after the "consensus" statement, the FDA's National Toxicology Program released an extensive peer-reviewed analysis in 2008 of the various studies of BPA and again concluded there was no reason for serious concern about its effects on human reproduction or development in adults or children (NTP, HHS, and NIEHS). The NTP used the term "some concern" to characterize the possible effects of BPA on fetuses. The term has never been defined, but in practice it's been used when the agency did not consider a chemical harmful or worthy of restrictions or health warnings; in effect, scientists say, it's been used as a code phrase to suggest further study. The NTP pointedly reached that qualified conclusion because the rodent studies were not "experimentally consistent"—some showed no problems and test results could not be replicated in many instances.

The EPA subsequently funded two additional multigenerational analyses. Both studies failed to support the low-dose hypothesis. The most recent analysis, which appeared in November 2009 in *Toxicological Sciences*, a leading scientific journal, was particularly definitive. Carried out at the EPA's Office of Research and Development in Research Triangle, North Carolina, it was specifically designed to cover a wide range of BPA doses. L. Earl Gray Jr. and his colleagues concluded that BPA is an extremely weak estrogen not worthy of being called an "endocrine disruptor." BPA was found to be so weak that even at levels of exposure 4,000 times higher than the maximum exposure of humans in the general population there were no discernible effects

(Ryan 2010). Gray's research mirrored findings by regulatory agencies around the world. The hodgepodge of low-dose endocrine disruptor studies is "inadequate," "not replicable," and "extremely limited" in value, Gray's team wrote, concluding, "BPA did not display any estrogenicity" (Gray Jr. 2010).

The first comprehensive FDA-sponsored study of pharmacokinetics of BPA in primates, which are biologically closer to humans than rodents, reached much the same conclusion. Among the findings of the University of Georgia and FDA researchers, published in the October 2010 issue of *Toxicology and Applied Pharmacology* (Doerge, et al. 2010):

- BPA does not accumulate in the body;
- BPA is efficiently metabolized by adult monkeys after oral exposure;
- The capability of neonatal monkeys to metabolize BPA is equivalent to adult monkeys, which suggests that neonates may not be more sensitive to the potential effects of BPA; and
- Primate results suggest that studies in rodents may over-predict health risks associated with BPA ingestion.

The head researcher, Daniel Doerge, a chemist at the EPA's National Center for Toxicological Research in Arkansas and a staff member on the EPA Science Advisory Board, supports no known horse in this race. In three papers released this year, he and his colleagues have found that newborns and infants can metabolize BPA much like adults do, that rats injected with BPA (as opposed to being fed it) overestimate human exposure and that current estimates of human exposures to BPA, which are exceedingly low, are likely to be accurate. His findings are a direct rebuke of the key assumptions underpinning the endocrine disruptor hypothesis.

In a reasonable world, the stream of comprehensive EPA and FDA reviews and studies, backed by consistent evaluations of BPA's relative safety by European health authorities, should quell concern over the low-dose, endocrine-disruptor, precautionary principle-fed hypothesis. But we don't live in a reasonable world. The renewed focus is now political. Both the House and Senate are entertaining bills banning the use of BPA in products handled by infants, and numerous states and localities have passed restrictions, including Minnesota, Maryland, Wisconsin, Connecticut, Washington, Vermont, New York, Albany County and the cities of Schenectady and Chicago.

Case Study: Atrazine—Weighing Risks and Benefits

Farmers have been known to say that the most important invention in the history of agriculture besides the plow is the herbicide atrazine. The odorless white powder is applied on farms to control a wide range of broadleaf and yield-robbing grassy weeds. Manufactured by the Swiss-based agrichemical company Syngenta and licensed in the United States since 1958, atrazine is part of the chemical family of triazine herbicides used on many fruits and vegetables, including nuts, citrus and grapes. It was among the first of what are called “selective herbicides,” which destroy weeds that would otherwise choke a crop and starve it of nutrients, but do not harm the crop itself. In combination with other products, it can help boost the efficacy of other weed killers. Yet it is considered so comparatively gentle by farmers that it can be applied even after a crop’s first shoots appear above the ground.

Almost half of the atrazine in use is applied in the U.S., where it is used on dozens of crops, including more than half of the country’s corn crop, 90 percent of its sugar cane and two-thirds of its sorghum. More than 160 million pounds of atrazine is produced annually. Although regulatory agencies have consistently determined that atrazine is safe as used, it has come under relentless attack by anti-pesticide groups and some university scientists, who are convinced that it poses potential health threats for aquatic animals such as frogs and, by extension, to humans. They are concerned that it might affect human reproduction and hormonal activity—that it’s an “endocrine disruptor”—making it equivalent to a ticking chemical time bomb.

Atrazine fits a variety of farming systems. It is credited as being a key factor in the transformation of farming from the relatively low-yield, massively labor-intensive activity that prevailed into the first half of the 20th century and through the dust-bowl Thirties into the

advanced, high-technology industry it has become today. It is the most widely used herbicide in conservation tillage systems, which are designed to prevent soil erosion. It has become a critical tool in the no-plow revolution that is helping to cut carbon pollution.

Atrazine conserves water because the stalks, husks and other crop residue from previous harvests are left on the ground and the soil is not plowed up. Less plowing means less use of oil-hungry farm machinery. Not turning over the earth to kill weeds also keeps huge amounts of carbon dioxide trapped in the ground, limiting CO₂ emissions. According to the U.S. Department of Energy, if no-till and other conservation methods were more widely adopted, carbon emissions could be reduced by forty to fifty billion tons, which is a sizable savings as it's estimated that approximately six billion tons of carbon are released from fossil fuels each year (U.S. Energy News).⁴

Some analysts estimate that 10 to 40 percent of sugar cane yield could be lost without atrazine. An EPA study concluded that atrazine boosts yields by 6 percent or more, saving corn farmers as much as \$28 per acre—more than \$2 billion in direct economic benefits, which could be the difference between solvency and bankruptcy for many. The report added that if atrazine were unavailable to corn farmers, the “yield loss plus increased herbicide cost may result in an average estimated loss of \$28 per acre” (EPA 2002). Another study looking at combined data from 236 university cornfield trials from 1986 to 2005 found that crops treated with atrazine yielded an average of 5.7 bushels more per acre than those treated with alternative herbicides (Fawcett

⁴ According to the DOE, “Researchers estimate that the extensive adoption of no-till agriculture, diversified rotations, cover crops, fertility management, erosion control and irrigation management can lead to the recovery of two thirds of the carbon that has been lost from the soil due to conversion of native ecosystems to agriculture and the use of conventional management practices.”

2008).

Not everyone agrees with those estimates, however. Tufts University economist Frank Ackerman, who has campaigned for tighter restrictions on atrazine and other chemicals and works closely with atrazine critics, wrote a controversial analysis in 2007 challenging the EPA study, claiming atrazine increases yields by as little as one percent (Ackerman 2007). In contrast, a recent analysis conducted for Syngenta by University of Chicago economist Don Coursey concluded that a ban on atrazine could cost corn farmers between \$26 and \$58 per acre. He estimated that as many as 21,000 to 48,000 farm and farm-related jobs could be lost, and the negative economic impact to the U.S. economy could reach as high as 5 billion dollars a year (Coursey 2010).

Studies and Regulation

Atrazine is one of the most assessed and regulated agricultural chemicals in history. There have been more than 6,000 studies on the herbicide, compared to the 100 to 200 safety studies generally required by the EPA before registering a product. It has long been considered safe because it has a short half-life, does not bio-accumulate in organisms, and reportedly induces abnormalities and deformities only at very high doses (UK Rapporteur Monograph 1996) (Solomon, et al. 1996).

Atrazine has been approved as safe in regulatory reviews throughout the world. No country has ever discontinued the use of atrazine based on evidence of health dangers—including the member states of the European Union. In 1996, when the EU first formally evaluated atrazine, its scientific reviews were positive: “It is expected that the use of atrazine, consistent with good plant protection practice, will not have any harmful effects on human or animal health or any

unacceptable effects on the environment,” the regulators concluded (UK Rapporteur Monograph 1996). However, in 2003, faced with arguments that there were lingering uncertainties about the hidden dangers of chemicals, EU officials reexamined the evidence under the precautionary principle. Although they could find no evidence that atrazine caused any harm, EU officials eventually concluded that water-monitoring data were insufficient to guarantee that trace levels of atrazine in water would not surpass the agreed-upon level that had been set by EU member states for all pesticides based on precautionary arguments, not proof of harm. Atrazine is not on any list of banned chemicals and could be re-registered if the necessary monitoring data could be provided to show that it was found in drinking water at the levels deemed safe by the EU (Brussels: Health and Consumer Protection Directorate-General 2003).

Other regulatory bodies, even those that incorporate precautionary standards, have not recommended that it be banned. In 2004 Canada, which has restricted BPA under a narrow interpretation of the precautionary principle, found atrazine safe (Health Canada 2004). The World Health Organization concluded in 1999 that atrazine does not cause cancer in humans (International Agency for Research on Cancer Monographs 1999) and reaffirmed the finding of its relative safety in 2010. Based on recent data reaffirming the relative innocuous hazard profile of atrazine, WHO dramatically revised the exposure threshold level, setting it 100 times higher than does the obsessively-cautious EU. (World Health Organization 2010). After an extensive review of the data in 2008, the Australian government concluded that it “continues to be satisfied that [atrazine] can be safely used ... subject to those conditions outlined on product labels” (Australian Pesticides and Veterinary Medicines Authority 2010). In 2010, faced with another claim that atrazine may be associated with birth defects, the Australian government examined the

latest research and reaffirmed its safety designation. It wrote on its Chemicals in the News website:

“Every year, a number of epidemiological studies describing correlations between certain human health or environmental findings and pesticide use are published. Because of the relatively low rate of occurrence of birth defects, epidemiological studies of this type offer some useful information and hypotheses. In the regulatory context, any causal link has to be established by more extensive investigations and targeted follow-up studies” (Australian Pesticides and Veterinary Medicines Authority 2010).

Atrazine has faced the most intense scrutiny in the U.S., where it has been almost continuously evaluated for decades. Although regulatory authorities that rely on long-established study protocols consistently had concluded that it presents no serious harm as utilized, aggressive campaigns by anti-chemical NGOs such as the NRDC, EWG, and the Pesticide Action Network (PAN) prompted another review in 2005. After one of the most intense analyses of any substance in history, the EPA formally relicensed it in 2006, declaring it safe when properly used.

Ban proponents, emboldened by the EU action, did not give up, however. The NRDC had sued the EPA in 2004 under provisions of several federal laws that the group claimed should have long ago led to a ban, but it eventually lost. When the Obama administration took office in 2009, the NRDC saw an opening to again press its case. In August of that year, it issued a scathing, well-publicized critique, accusing the agency of ignoring the presence of atrazine in drinking water and in natural watersheds across the Midwest (Natural Resources Defense Council 2009).

The media gave the report enormous attention, reinvigorating advocacy blogs and stirring politicians.

In October 2009—barely three years after the EPA had completed one of the most exhaustive scientific investigations of a commercial product ever undertaken—the agency announced it would evaluate atrazine once again, citing the NRDC report as its reason. “Our examination of atrazine will be based on transparency and sound science, including independent scientific peer review,” said the head of the Office of Prevention, Pesticides and Toxic Substances (EPA 2009). The EPA subsequently convened a series of “scientific advisory panels” (SAPs), composed of yet another team of independent scientists, to reexamine the chemical on an accelerated schedule.

Harm Versus Risk

Atrazine is one of many hundreds of compounds that can be detected in water. Every year an estimated 495,000 pounds of the herbicide become airborne and fall with rain, sometimes hundreds of miles from the source. Although it breaks down quickly, it has nonetheless been detected at infinitesimal levels—measured in parts per billion (ppb)—in lakes, streams and other waterways as well as in drinking-water systems in agricultural areas.

Does atrazine at the residue levels found in drinking water in the U.S., Europe and elsewhere pose genuine threats to human health, as is sometimes reported? The controversy revolves around perceptions of chemicals and risk. The mere presence of a compound in water does not constitute a threat. Scientists have long used the “weight of evidence” approach to assess potential toxicity, which requires balancing complex and often conflicting evidence. They attempt to discover the exposure level at which a chemical does not harm an animal—the “no

effect” level—and then set human safe exposure standards that are tens, hundreds or thousands of times lower than this “no effect” amount. This built-in safety cushion ensures with a huge margin that no one is exposed to harmful levels of a regulated substance. This is the ultra-high threshold standard used by the EPA and regulatory bodies to assess chemicals, including atrazine.

The gap between the public’s perception of harm and scientific determinations of risk is often significant, as a 2008 “investigation” by the Associated Press that went awry illustrates. In a widely circulated article, the news organization found a vast array of pharmaceuticals in the drinking water of at least 41 million Americans. That investigation touched off a panic of sorts in New York City, long proud of its pristine drinking water, and prompted a study by the city’s Department of Environmental Protection. Released in May 2010, the city report indeed noted that investigators found traces of chemicals—but the levels were harmless, measured mostly in the parts per trillion (New York City Department of Environmental Protection 2010). One part per trillion is equivalent to one drop of water in 26 Olympic-size swimming pools, officials noted. “Just because you detect something doesn’t mean that it’s a problem,” said Cas Holloway, commissioner of the DEP (Saul 2010).

Each regulatory body sets its own exposure standard for the annual average concentration of a chemical. The standards are somewhat arbitrary. The EU sets the cut off for any agricultural at 1 ppb regardless of its chemical properties or hazardous potential. The U.S. EPA sets the atrazine standard at 3 ppb based its classification as a carcinogen, which scientists now believe it is not. Canada’s standard is 5 ppb, the United Kingdom’s is 15 ppb and Australia’s is 40 ppb. In October 2010, after an extensive review of the various international standards and the latest

scientific data on atrazine, WHO concluded its standard was far too restrictive, and revised it to 100 ppb (World Health Organization 2010).

On occasion, atrazine has been detected in drinking water in various communities at very low concentrations. A 2006 U.S. Geological Survey reported that approximately 75 percent of untreated stream water and about 40 percent of all groundwater samples from selected agricultural areas from 1992-2001, mostly in the corn-growing Midwest, contained miniscule traces of atrazine that occasionally spiked for short time periods at over 3 ppb (Gilliom 2006). Some NGOs cited the report in sensational news releases as evidence of atrazine's dangers. But that is not what the study showed, according to scientists. It concluded that "[C]oncentrations of pesticides detected in streams and wells were usually lower than human-health benchmarks, indicating that the potential for effects on drinking-water sources probably is limited to a small proportion of source waters."

The EPA's 3 ppb annual standard for treated drinking water was derived using a one thousand-fold safety factor that sets a level shown to have no health effects in laboratory animal studies. To put this in perspective, it is estimated that even if a person were to drink thousands of gallons of water containing 3 ppb of atrazine every day for a lifetime, he or she would still not be exposed to amounts shown to have effects in lab studies. Said in another way, the 2006 survey found miniscule erosion in the huge safety cushion. Using the standards in place in the U.S., Canada, Australia or under the new WHO guidelines, the concerns expressed by NGOs appear alarmist

Under an agreement with the EPA, Syngenta conducts weekly testing during the growing season

of any drinking-water system that has been found to contain annual atrazine and metabolite levels above 2.6 ppb (which is equivalent to an annual atrazine level of 1.6 ppb). In general, the already low levels of the herbicide found in water have been trending down over the course of the last 10 to 15 years. According to the EPA, concentrations in raw water declined significantly between 1994 and 2006 at 103 frequently monitored sites (Sullivan, et al. 2009). However, in its 2009 report, the NRDC crunched the raw data and found that three local water systems—two in Illinois and one in Indiana—in previous years had, on occasion, temporarily exceeded the 3 ppb EPA limit by fractional amounts. In each of the three cited cases, the annual averages in these communities did not exceed the EPA's 3 ppb annual limit.

Those findings, noted in press releases and widely disseminated, created the misleading belief that these drinking water systems were somehow unsafe. That's not the case. The EPA was aware of the occasional spikes. Based on decades of tests on atrazine, it did not consider these occasional spikes a safety threat for either short-term (acute) or long-term (chronic) potential exposure. However, in its sensational report, the NRDC characterized the spikes as "particularly alarming," claiming that "potential adverse effects [are] associated with even short exposures to atrazine" (Natural Resources Defense Council 2009)—an opinion, while sensational and widely circulated, has not been confirmed in any study or accepted by the EPA. And again, in the context of the latest scientific data, as incorporated in the new WHO standard, the NRDC's position comes across as alarmist.

Steve Bradbury, deputy director in the Office of Pesticide Programs at the EPA, said the monitoring program has never found atrazine levels approaching the 90-day or one-day maximums (Souder 2009). A cumulative risk assessment for triazine pesticides (the family of

chemicals that includes atrazine) published by the EPA in 2006 concluded, “Risk assessments for cumulative exposures to triazine residues via drinking water based on currently registered uses of atrazine and simazine are not of concern” (USEPA Office of Pesticide Programs, Health Effects Division 2006).

The “Endocrine Disruptor” Hypothesis Controversy

As in the case of BPA, atrazine’s comparatively benign toxicological profile has long posed a challenge for its critics. University of California herpetologist (research focus on amphibians) Tyrone Hayes is the most ardent. The Berkeley professor began studying atrazine in the 1990s with research funded by Syngenta, as part of its due diligence. Hayes and the company parted ways in the late 1990s. He claims he came to suspect that atrazine was interfering with the natural production of hormones, and decided to pursue his studies independently.

In 2002, Hayes published a study that ban proponents had been hoping for. His team focused on amphibian populations, which have been in worldwide decline for decades, baffling scientists. In lab experiments that exposed clawed frogs to lower doses of atrazine, the researchers produced males with ambiguous genitalia and squeaky, soprano-like croaks—hermaphrodites. “We hypothesize that atrazine induces aromatase [a protein that spurs the production of the female hormone estrogen] and promotes the conversion of testosterone to estrogen,” the Hayes team wrote (Hayes, et al. 2002).

Hayes’s study set off an immediate firestorm. It was released at the same time as another team, in a much larger study funded by Syngenta but also operating independently, found no meaningful link between atrazine exposure and abnormalities. Keith Solomon of the University of Guelph, Ontario, Canada, found that lower levels of atrazine did not induce aromatase, a result

that, if true, would undermine Hayes's conclusion (Renner 2002). The controversy, which persists today, was fully engaged.

Whereas precautionary thinking is easy to grasp and plays into our instinctual fear of the unknown, the concept of relative risk is very hard for most nonscientists, including many journalists, to get their minds around. Branding any chemical as a toxic "endocrine disruptor" is about as useful as describing a car as "fast." Relative to what? Under what conditions? The question for regulators remains: how much of a substance causes a deleterious effect? To put this in perspective, vitamin D—an essential vitamin for life—has about the same toxicity as arsenic. The 2005 Dietary Guidelines for Americans recommends that healthy older adults consume 1000 IU/day, whereas in adults, taking 50,000 IU/day for several months can produce toxicity. This 50:1 ratio would surely confound regulators, if the chemical were not essential to human life.

Knowing the effect and the dose at which that effect can occur is the evidence-based standard used by the EPA to regulate chemicals. The precautionary principle, on the other hand, asks only for effect and then demands action without the context of exposure. The only significant science-based question is whether a particular substance is harmful at the trace level at which it is present in the human body. Many synthetic chemicals labeled endocrine disruptors are millions of times less potent than estrogen or testosterone and simply do not have the "punch" to affect the endocrine system very much. For atrazine, the relevant factor is potency relative to estrogen or testosterone. Studies that apply classic risk analysis have consistently shown that "a risk to human health [from atrazine is] essentially nonexistent" (Cooper, et al. 1996 is one of numerous studies).

The case against atrazine rests largely on the integrity of the central body of research by its chief critic, Dr. Hayes. For example, a widely circulated joint polemic issued in January 2010 by the Land Stewardship Project and the Pesticide Action Network cites Hayes more than 50 times and includes a question-and-answer section with him in which he outlines his allegations (Land Stewardship Project and Pesticide Action Network 2010). Although his reports have been widely criticized, no mention is made of alternate perspective, conveying the false impression that Dr. Hayes's views are widely embraced by mainstream scientists.

Many independent scientists have raised doubts about the reliability of his data and his conclusions, viewing him more as an activist than an objective researcher. "Atrazine has been used widely in South Africa for the past 45 years, and our studies showed that *Xenopus* are doing equally fine in agricultural and nonagricultural areas," zoologist Louis du Preez of North-West University in South Africa noted in response. African clawed frogs do not appear to be suffering from the herbicide in their native habitats. "If atrazine had these adverse effects on *Xenopus* in the wild, surely we would have picked it up by now" (Biello 2010).

The EPA and scientists on the government's independent SAPs have doggedly tried to replicate Hayes's findings, but to no avail. In 2005, the agency published a 95-page white paper, concluding that his work and many other studies drawing similar conclusions about atrazine's impact on amphibians were "scientifically flawed." Anne Lindsay, then the deputy director of the Office of Pesticides, testified that the EPA "has never seen either the results from any independent investigator published in peer-reviewed scientific journals or the raw data from Hayes' additional experiments that confirm Dr. Hayes' conclusions." According to Lindsay, "The existing data are insufficient to demonstrate that atrazine causes such effects [aromatase

induction]” (Statement of EPA’s Anne E. Lindsay, Minnesota House of Representatives 2005).

The controversy did not fade, however, as advocacy groups continued to cite Hayes’s findings and press regulators to ban atrazine. Facing intense public scrutiny stirred by the media, the EPA required Syngenta to fund extensive additional independent laboratory studies carried out in two separate labs in the United States and Germany—the most extensive reviews ever undertaken on atrazine. Both studies refuted Hayes’s conclusions. Biologist Werner Kloas of Humboldt University in Berlin found no impact on clawed frogs at concentrations comparable to those investigated by Hayes. He questioned the single exposure level used by Hayes in his study and the lack of measurement of female hormone levels in the affected frogs. Kloas’ findings are particularly noteworthy because he has publicly expressed his view that a chemical should be banned for precautionary reasons if there is evidence, however incomplete, questioning its safety (Biello 2010).

After a SAP review of all the data, in 2007, the EPA concluded, “There is no compelling reason to pursue additional testing” (EPA 2007). But that definitive assessment did not deter critics. Although the two Syngenta-funded studies were conducted under the strictest application of EPA’s GLP Standards and were thoroughly audited and inspected data point by data point by the EPA, advocacy groups dismissed them as inherently not credible—as they have all studies in which the industry participated or funded.

That sweeping denunciation illustrates a lack of understanding of the process of evaluating and approving chemicals, notes Amy Kaleita An agricultural and biosystems engineer at Iowa State University. Chemical companies fund large-scale studies not to mollify the media but because

they are necessary to meet federal guidelines. In the case of atrazine, the Federal Insecticide, Fungicide, and Rodenticide Act places the burden of proving safety on pesticide companies. For a chemical such as atrazine to be approved, it must undergo a battery of tests designed by the EPA and often carried out by independent laboratories, which follow rigorous, internationally recognized Quality Assurance Protocols. The data is available to EPA auditors, who often review the study methodology and conclusions in fine detail. If the EPA determines that the study protocol is in any way deficient, it requires companies to fund additional tests.

By contrast, the peer review process is not very efficient in sorting out quality from bad peer-reviewed papers. Journal articles do not require editorial oversight or government audit. A manuscript often contains only a few paragraphs explaining the methodology behind the study and little information, if any, about quality assurance procedures. Reviewers rarely have access to the raw data summarized in the paper, and study authors decide for themselves whether to respond to reviewer comments and questions, let alone dialogue with them. Atrazine, Kaleita says, highlights “[t]he absurdity of dismissing industry funded studies in favor of peer review. (Kaleita, 2010)

Hayes’s work has been peer reviewed for journal articles, but the data remain in a proverbial black box to regulators and independent scientists. Because of the storm of controversy fanned by the NRDC and other advocacy groups, in 2008 the Australian government’s Department of Environment, Water, Heritage and the Arts reviewed all of Hayes’s studies. Its conclusion: “Atrazine is unlikely to have an adverse impact on frogs at existing levels of exposure” (Australian Pesticides and Veterinary Medicines Authority 2010). That same year, in experiments that closely replicated Hayes’s study outline, endocrinologist Taisen Iguchi at the

Okazaki Institute for Integrative Bioscience (Japan) and colleagues raised tadpoles in various concentrations of atrazine and found no hermaphroditic frogs (Oka, et al. 2008). After reviewing the data, endocrinologist Robert Denver of the University of Michigan, well recognized for his independence, commented that the experiments “appear to be carefully executed and the data thoughtfully interpreted. Overall, this appears to be a sound study that does not support the view that atrazine adversely affects amphibian gonadal development through an estrogenic action” (Renner 2008).

Keith Solomon, by then head of the Centre for Toxicology at the University of Guelph, reviewed more than 130 recent studies on atrazine for *Critical Reviews in Toxicology*, a well-regarded international journal. The team’s conclusion, published in 2008: Most studies found atrazine had no significant effects, and even in cases where effects were found, they were not substantial enough to warrant concern:

“We have brought the results and conclusions of all of the relevant laboratory and field studies together in this critical review. . . . Based on a weight of evidence analysis of all of the data, the central theory that environmentally relevant concentrations of atrazine affect reproduction and/or reproductive development in fish, amphibians, and reptiles is not supported by the vast majority of observations. The same conclusions also hold for the supporting theories such as induction of aromatase, the enzyme that converts testosterone to estradiol. For other responses, such as immune function, stress endocrinology, parasitism, or population-level effects, there are no indications of effects or there is such a paucity of good data that definitive conclusions cannot be made” (K. Solomon 2008).

Although a massive meta-analysis published in fall 2009 raised some concerns about the effects

of atrazine, it pointedly noted that Hayes and only Hayes has found that atrazine increased aromatase and that no study has found it affects vitellogenin levels, a protein that should be present if atrazine was seriously impacting the endocrine system. Its conclusion: “These data do not support the hypothesis that atrazine is strongly estrogenic to fish” (Rohr and McCoy 2010).

Most recently, in March 2010, Hayes was the lead author on a paper published by the National Academy of Sciences arguing that atrazine demasculinized frogs throughout all life stages, from tadpole to adult, when they were exposed to a single dose below 3 ppb. Hayes and his team speculated that the atrazine was absorbed through the frogs’ skin and turned on a gene that in male frogs should stay off—it converted testosterone into estrogen, flooding the frog’s body with the wrong chemical signal (Hayes, et al. 2010). No other research team, independent or industry funded, has found similar effects. Australian officials reviewed the new study, found it wanting, and said there was not sufficient evidence to reconsider its current conclusion that atrazine is safe as currently used (Australian Pesticides and Veterinary Medicines Authority 2010).

The EPA has been eager to review the data from Hayes’ studies, but the Berkeley scientist has steadfastly refused to cooperate with regulators. After years of frustration, in a May 2010 letter, the agency’s Donald Brady, director of the EPA’s Environmental Fate and Effects Division, Office of Pesticide Programs, issued a highly unusual rebuke to Hayes in a response to an inquiry from Illinois state representative Dave Winters, who had contacted the EPA after the Berkeley scientist testified before the state legislature urging a ban on the pesticide:

“As with most reviews conducted by the EPA, the analysis of data and studies is not limited to a single individual [at EPA] but rather involves interdisciplinary

scientific teams and multiple rounds of peer review. You [Winter] asked whether EPA was in agreement with Dr. Hayes' findings. . . . I regret that the EPA science staff in the Office of Pesticide Programs' EFED could not properly account for the sample sizes and study design reportedly used by the Berkeley researchers. As a result, we were unable to complete any independent analysis to support the study's conclusions" (Letter from U.S. EPA's Donald Brady to Illinois State Representative Dave Winters 2010).

One would think that questions raised about Hayes's studies by internationally respected toxicology laboratories and regulatory agencies would make headlines at least comparable to the scare stories that regularly appear after the publication of each of his controversial papers—but they didn't. Why have journalists refused to provide a balanced perspective on atrazine in particular and chemicals in general? Simply stated, many reporters are poorly schooled in science. They often do not have the sophistication or inclination to apply weight of evidence criteria or critically parse science from ideology. While new claims that one product or another contains harmful chemicals often results in a sensational front-page story, because of the journalist's default mindset, a study that shows a chemical is safe or has few effects is often ignored or relegated to the back pages. What is the news value in the headline "Atrazine Found Safe; Scientists Conclude Fears Overblown"?

A Precautionary Future?

The scientific evidence strongly suggests that atrazine does not present a serious danger to aquatic wildlife, let alone humans. Unable to make headway on the science, atrazine opponents have turned to politics and litigation. Lawsuits have been filed against Syngenta and other

corporations that market and manufacture products containing atrazine. Farmers face ongoing activist campaigns intended to pressure U.S. regulators into adopting more precautionary policies. If the EPA imports and implements this precautionary model, atrazine and other chemicals found safe by classic weight of evidence risk assessment studies would be subject to what would amount to a political review of their acceptability. Such a seismic shift in regulatory standards could lead to restrictions based on suspicions and fears rather than scientific evidence. Trade-offs, such as the higher food costs and the damage to America's farming economy and international competitiveness that a ban would inflict, could be downplayed or ignored. If the precautionary view prevails, the unintended consequences could include more soil erosion, less sustainable farming, more environmental degradation—and a hungrier world.

IMPLICATIONS FOR PUBLIC HEALTH

Policymakers use what is called risk-risk analysis to evaluate chemicals. They consider two key questions. At what levels could a substance cause harm? What would be the possible unintended consequences if a useful chemical were pulled off the market? The only justification for banning BPA or any chemical would be if it could be shown, based on empirical science, that current risks outweigh established benefits.

Benefits of a Chemical Exceed Risks

When asked in January 2010 whether the low estrogenic impact of BPA warranted further restrictions, FDA Deputy Commissioner Sharfstein responded as a scientist, carefully balancing costs and benefits. “FDA does support the use of bottles with BPA because the benefit of nutrition outweighs the potential risk of BPA,” he said. (Strictly speaking, the FDA does not consider benefits in its analyses of food packaging, like polycarbonate containers; packaging should be approved as long as it meets safety standards and regardless of the benefits of the product it contains.) As he noted, restricting BPA could have the opposite effect; its benefits would be lost while resources that could otherwise be devoted to addressing established health risks would be wasted on trying to eliminate low-potential risks.

It is important to do risk-benefit and risk-risk analyses—balancing the actual and potential risks of various chemicals with their utility against potential harms. But reflexively responding to public or NGO fears by banning or otherwise limiting the use of certain chemicals that have not been demonstrated to pose actual risks to humans will not improve public health. In some cases, an untested chemical may end up replacing a relatively innocuous substance, such as BPA. Undoubtedly some replacements could end up causing actual harm while the original chemical

only posed theoretical harm based on experiments using animals in high-dose studies. Some regulations do not address actual scientific and health risks, but have been put in place almost solely in response to advocacy campaigns.

For example, the accumulation of oil in the Gulf of Mexico in the wake of the BP disaster has led to widespread concerns that fish are contaminated while tests indicate only limited areas have been seriously affected. People just can't shake their fear of chemicals. The problem has been encouraged in part because of a history of government "consumption advisories," which warn the public about eating fish containing low levels of chemicals, such as PCBs or mercury, for which little evidence exists that they cause harm to humans at low levels (consumption of unusually large quantities of fish containing methylmercury may lead to levels that reach or exceed recommendations; that would suggest caution, but effects would be highly likely). In general, the health benefits of eating fish, particularly in preventing the nation's biggest killer, heart disease, are demonstrated and significant, far outweighing the miniscule potential dangers (Mozaffarian and Rimm 2006).

The paradigmatic example of an overreaction is what happened to DDT, the insecticide targeted by Rachel Carson. DDT remains the totemic villain of the environmental movement, but it has saved more lives from malaria and other insect-borne diseases than any other chemical. In retrospect, the ban on DDT has proven to be a mistake of tragic proportion. In the early 1960s, several developing countries had nearly wiped out malaria. After they stopped using the insecticide, other control methods have had only modest success and malaria came raging back. In one of many examples, in Sri Lanka (then Ceylon), DDT spraying had reduced malaria cases from 2.8 million in 1948 to 17 by 1963.

After spraying was stopped in the wake of the uproar after the publication of *Silent Spring*, the number of cases exploded to 2.5 million. Malaria still kills about one million people a year, mainly children, and primarily in Africa, despite the decades-long effort to eradicate it without DDT. Many scientists and some environmental groups, including the Sierra Club and the EDF, have recently urged that the use of pesticide be reconsidered, because its effectiveness is unrivaled and it causes minimal collateral damage when properly applied. In 2006, after millions of preventable deaths, the World Health Organization reversed course and endorsed the use of the insecticide as one effective way to control malaria (Roberts 2010).

Given the state of the science at the time Carson wrote her book, one might generously make the case that her concerns about the potentially unknown effects of synthetic chemicals on human health were not unwarranted. Some key facts were unclear. But after four decades chasing the potential risks of DDT and certain other chemicals without measurably improving world health, and in some cases degrading it, her followers in the environmental movement bear the responsibility of wasting billions of dollars and destroying millions of lives.

Risks of Replacement or Amelioration Exceed Benefits

There were also other unintended consequences of banning DDT. At the time of the ban, William Ruckelshaus noted that methyl parathion would be the primary replacement. That decision was a lethal mistake. After several deaths linked to the chemical, the EPA in 1999 acknowledged that parathion is “hazardous to workers,” even to those wearing protective clothing, and accepted voluntary cancellation of many of its registered uses. The EPA, when confronted by scientifically naïve if well-meaning activists, had put expediency over saving lives.

The effort to remove asbestos from the walls of schools has addressed dangers but created others. Asbestos had been shown to cause lung cancer and mesothelioma in workers who had installed it (National Cancer Institute 1995). When asbestos was found in many public buildings, widespread concern erupted (Mossman, et al. 1990). The EPA jettisoned traditional risk analysis based on quantitative levels of exposure. Under the Asbestos Hazard Emergency Response Act of 1986 (U.S. Congress 1986), the EPA required all public school districts and private schools to inspect school buildings for asbestos and develop amelioration plans in a timely fashion. Because school districts, fearing suits, took the directive as an order for removal, in effect the EPA took the expensive and potentially dangerous position that the presence of any asbestos in any part of a school constituted an unacceptable hazard. As the EPA now notes on its website, “intact, undisturbed asbestos-containing materials generally do not pose a health risk.” Although the EPA now says removing the asbestos could cause more harm to workers and the general public than leaving it in place, NGOs and tort lawyers continue to harangue public officials to remove all traces of asbestos, regardless of the financial or environmental costs.

The movement to replace chlorine with chloramine has also proved misguided in some cases. Chlorination reduces microbial agents of disease. Environmental activists in Washington, D.C., citing high-dose animal studies on rats and mice, claimed it was harmful and had it removed from the water system (International Joint Commission 2003). There is no question that high dose chloroform can cause liver damage and is a precursor to liver cancer, but to suggest the trace levels cause cancer in humans is irresponsible and incites needless public fears. Moreover, chloramine causes the lead scale on pipes to dissolve into the water, creating a genuine neurotoxic hazard (Switzer, et al. 2006). Thus, a hypothetical danger was replaced by a real risk.

A campaign by consumer groups to remove diacetyl, a natural byproduct of fermentation found in butter, from artificially flavored buttered popcorn after it was found to cause a rare, serious lung disease in a small number of production workers who inhaled it in large quantities has led to unintended consequences. The European Food Safety Authority has evaluated its health effects on popcorn-eating consumers and found it safe (EFSA 2004). Instead of focusing on the actual threat, the occupational hazard, many activists warn consumers in overheated Web posts to be suspicious of scientific assertions that eating popcorn flavored with diacetyl is safe. Why?

Because the FDA and even physicians use lax standards in evaluating chemical exposure, says the Environmental Working Group. “No one knows how many chemicals with potential dangers lurk in the everyday objects we use and foods we eat,” it writes in an ominous story on diacetyl (Environmental Working Group 2010). Before its campaign against BPA, the *Milwaukee Journal Sentinel* focused its ire on diacetyl. “Snack could be toxic,” it sensationalized in a headline in one of numerous stories. In fact, the only consumer case known to date involves one Colorado man who reportedly ate at least two bags of buttery microwave popcorn almost daily for more than 10 years was diagnosed with the same disorder (Rutledge 2007). Facing the prospect of a consumer backlash, manufacturers began replacing diacetyl with an untested substitute, pentanedione. Now new studies show pentanedione is worse than diacetyl, which is actually appears harmless unless abused. (Hubbs, et al. 2010)

Psychology of Risk Perception

In the face of human irrationality and recklessness, can anything be done to restore balance to the discourse about chemicals? Why are so many people, who are educated and otherwise rational, so deathly afraid of chemicals? Reporters do not take to the cyberwaves to expound on the latest

discovery that fruits and vegetables are nutritious and safe. It's bad news, all the time, and it creates paranoia and chemophobia. As the New Jersey mother mentioned in the Introduction, Pamela Davis, remarked, "Once you're aware of one thing it just spreads and you start questioning everything. You can drive yourself absolutely crazy trying to keep your baby healthy." But even the relentless noise of the 24/365 media machine cannot completely account for the persistent fear that even the tiniest concentration of a synthetic chemical poses serious dangers. Clearly, our minds have a difficult time weighing rational versus irrational risks.

By now most people are familiar with the sadly comical DHMO scare. A controversy erupted in the 1990s when it was circulated on the Internet that the chemical dihydrogen monoxide had been linked to a range of medical and environmental problems, including excessive sweating and vomiting, with confirmed reports that it had been found in tumors of terminal cancer patients. A website, www.dhmo.org, documented its many dangers: It's a ubiquitous chemical and a major component in acid rain that could cause severe burns in its gaseous state, prove fatal if accidentally inhaled, contribute to erosion, and decrease the effectiveness of automobile brakes. There were proposals to "ban this toxic substance" in Australia and in localities in the United States. For the scientifically literate, of course, DHMO is the chemical formula for water. The biggest driver of fear is the unknown and that's what some activists prey upon, be they from NGOs, academic laboratories or social networking sites.

There is also a gap between perceived and actual risk. Risks that are unfamiliar or under someone else's control or are hidden—How much pesticide residue is on my child's broccoli? —are considered far more dangerous and frightening than perceivable hazards, even when they are less threatening. Former professional football coach and broadcaster John Madden refuses to fly

but regularly drives cross-country in his trailer home, which is a more dangerous way to travel. As the science journalist David Ropeik has written, it's helpful to acknowledge that the process of assessing risks is not logical. People make mental shortcuts to deal with information overload, the challenge of processing conflicting risks. For example, those whom he calls "pure food obsessives" believe that "everything God (or Nature) designed is good for you." They often default to irrational beliefs, even to their peril. He cites the case of people who drink raw milk despite evidence that the "all natural" version occasionally contains deadly *E. coli* mixed with a daily dose of calcium (Ropeik 2010). For whatever reason, many people are hard-wired to believe that risks in nature are somehow less threatening than the ones created by man.

Trust in Scientists and Science

Public anxiety over perceived environmental risks threatens to overwhelm sound scientific analysis, leading to poor public policy decisions and creating a serious obstacle to innovation and the necessity to rapidly commercialize scientific advances. How do we elevate the discussion so the public is best served when it comes to understanding the risks and benefits of chemicals?

There are no easy answers. Justified or not, confidence that government officials and corporations will serve the public interest is extremely low. From restrictions on stem cell research to "crackdowns" on agricultural chemicals, politicians have often put personal, religious and ideological views ahead of science. In that light, restoring a measure of balance in the discussion of the role of science and chemicals in our society is a daunting challenge.

Although most of us regard science an invaluable tool for protecting and enhancing life, those in the grip of chemophobia often consider it a tool of greedy corporations empowered by institutional indifference. The cynicism is not entirely unjustified. There have been numerous

environmental catastrophes marked by corporate recklessness, with government asleep at the switch, from Minamata Bay to mines in West Virginia to oil exploration and safety problems. It's no wonder, in this context, that conspiracy theories and misinformation about the alleged dangers of chemicals have found a fertile home in cyberspace, media reports and in the minds of so many people.

As recently as the 1980s, the public relied on a limited stream of respected sources when it came to making sense of their health concerns: doctors and medical professionals; the mainstream media, including TV networks and local stations, major newspapers and key magazines; and government agencies staffed by what we assumed were independent, career scientists. Today, there are tens of thousands of "news generators," many of them eager to get attention by presenting alarmist views.

Alternative medicine is flourishing and oversight agencies are often perceived as incompetent, corrupted or corruptible. Scientists may retain a measure of the public's trust, but there are concerns that many of them are captive to industry or are otherwise compromised.

Another driver is the U.S. litigation system, in which tort lawyers trolls for potentially lucrative class action suits. Lawyers comb the news trying to identify an industry or company that could pay for the consequences of contracting an alleged disease. These are tempting targets, especially in key jurisdictions notoriously sympathetic to class action litigation.

Educators do a poor job of teaching biology, chemistry, math, physics, and risk analysis essential to an understanding of science and technology. Americans are bombarded by stories about

pesticides, air pollutants and the like, but they are not educated to the risky hazards of daily life, from over-eating to unsafe sex. We are not providing students with the skills to differentiate between theoretical dangers, such as those embodied in cancer risk assessments from chemical exposures, and real (actuarial) risk, such as the odds of contracting cardiovascular disease from a fatty diet. Consequently, our educational system remains under constant attack by conservatives and liberals intent on shaping science to their personal ideologies.

Irrationality is an inherent part of the human condition. People believe what they want to believe. Even the well-educated embrace cherished dogmas, like “natural is always safer and better.” This extreme precautionary perspective fails to assess natural and human threats on the same basis. People tend to routinely ignore the potential benefits of technology, in effect favoring nature over humanity. Many people do not appreciate that the risks created by technological stagnation are often at least as real as those caused by technological advancement.

One way to at least start the process may be for scientists and the organizations that represent them to aggressively engage in a vigorous and coordinated public dialogue about uncertainty and risk. To assess how scientists perceive the risks from exposure to commonly-encountered chemicals, the Society of Toxicology teamed with George Mason University’s Center for Health and Risk Communication and its affiliated Statistical Assessment Service (STATS) to survey more than 900 toxicologists. In contrast to public opinion, only 33 percent ascribed significant risks to food additives and just one-in-four to cosmetics. By and large, toxicologists challenged the alarmist views of some environmental activists about which chemicals or exposures are most dangerous. Phthalates were considered high risk by 11 percent; BPA by 9 percent; and Teflon by 3 percent. Smoking (89 percent); second-hand smoke (44 percent); mercury (37 percent);

aflatoxin, a naturally-occurring fungus found in peanut butter, (29 percent); and exposure to sunlight (26 percent) were all considered far more dangerous. Fewer than one out of four believed that regulation should be guided by the precautionary principle and three-quarters said that the U.S. system for evaluating chemicals is superior to the European system. (STATS 2009)

Scientists are most concerned by the politicization of research. Two-thirds believe the peer review process has become too politicized; three-fourths believe scientists should restrict public statements to their areas of expertise; and a solid majority fault both the media and regulators for not doing a balanced job in explaining chemical risk to the public. The findings questioning media credibility were echoed by a recent poll of more than 2,500 members of the American Association for the Advancement of Science by the Pew Research Center, 76 percent of whom believed that news reports fail to distinguish between scientific findings that are well founded and those that are not (Pew 2009). Some 48 percent say reporters regularly oversimplify science issues. Few journalists seem to be able to distinguish between the concepts of actual dangers and potential risks.

Most scientists are aware of the widespread misrepresentation of risk by the media and the policy problems that it causes, but do not speak out. Scientists have largely remained silent when the public discussion turns to the trade-off of benefits and risks of chemicals. They are often unwilling to engage controversial issues as that could endanger their funding and research. The consequences of not challenging this misinformation are severe. The public interprets the unwillingness of scientists to engage those who campaign against chemicals as an implicit validation of their dangers. Those who do brave to speak out are often left isolated or branded as industry apologists. Maybe the best we can hope for is that brave scientists, scientifically literate

journalists and government officials who are responsible for translating science into regulatory policy will take the public's best interest into account. This perspective needs to be presented to legislators so they have information necessary to resist the irrational and often regressive impulses stirred by the scare tactics that are so common today.

Throughout history, scientific innovations and discoveries have been subject to criticism and resistance. It is primarily the fear of the unknown that fuels this sentiment. This is not to say that reasonable concerns regarding scientific innovations should be ignored. Appropriate safeguards should be implemented while adopting the latest technology. But we have to recognize, and educate the public and public officials, that most activities involving technology will have undesired effects as well as desirable ones. Fear of the unknown and exaggerated precautions shouldn't be invoked to impede scientific progress. Had it not been for a stream of scientific innovations throughout history, the world today would not be able to support seven billion people living in dynamic and complex community systems. Science and technology have improved our lives in more ways than we can imagine, and chemicals have played a key role. Let's hope that continues.

APPENDIX: COMMON MYTHS AND FACTS ABOUT CHEMICALS

Myth #1: A chemical-free world would be safer and healthier.

A chemical-free world is not possible. Everything—people, plants, animals, rocks, cars, air—is made up of chemicals. Some of these chemicals occur in their natural state and others are produced by combining naturally occurring chemicals.

Chemicals are everywhere—in living things, in inanimate parts of the environment and in the products vital to our health and quality of life. The natural world operates through the interactions of a vast array of chemicals. For example, humans need the chemical oxygen to survive. Plants, on the other hand, need carbon dioxide to grow and flourish. Thus the chemical waste product of one form of life is the raw material for another. Even beneficial chemicals are dangerous at high levels. We need some 20 percent oxygen in air, but humans exposed to 100 percent oxygen for more than 24 hours will suffer massive lung damage.

Humans depend on many other types of chemicals including proteins, carbohydrates, fats, metals and vitamins. These are supplied by food. The chemicals in the food we eat are utilized as raw materials for our growth and functioning. However, because humans are so complex, some of the chemical processes needed for these activities can malfunction. As a result, humans are subject to a variety of diseases that reflect excesses or deficiencies in these essential chemicals. For example, diabetes can result from the lack of production of the chemical insulin. Fortunately, it is now possible to make insulin synthetically and add this chemical to humans to counteract the effects of diabetes.

Thus, we are dependent on synthetic, as well as natural, chemicals for treating disease and improving both longevity and the quality of life. Both natural and synthetic chemicals are integral to all aspects of modern life. For example, natural chemicals in petroleum power cars, trucks and other vehicles, providing us with mobility and access to foods and goods from faraway places. Synthetic chemicals are critical to the functioning of the cornucopia of electronic devices, including computers and cell phones, giving us the ability to communicate around the globe instantaneously. There is no such thing as a chemical-free product and, indeed, chemicals are essential to human life and to our standard of living. Not only is a chemical-free world unachievable, it would be undesirable if it were possible.

Myth #2: Synthetic chemicals are dangerous; natural chemicals are safe.

All chemicals, whether synthetic or natural, have the potential to cause harm to people under the right circumstances. There are no nontoxic chemicals. Chemicals differ only in the types of toxicity they can cause and the exposure level at which these effects occur.

Many natural chemicals are toxic at high doses, including those in the food we eat and the water we drink. For example, a number of chemicals that occur naturally in our diet have been shown to be carcinogenic to rodents at high doses. Others, such as compounds found in soy products, can cause effects similar to those of human hormones. Thus, natural chemicals that are critical for life may also cause harm if humans are exposed to them under certain conditions. Similarly, other natural chemicals, such as arsenic, have been shown to cause adverse effects in humans when found in high levels in drinking water. The toxicology literature is rich with stories of “endemic diseases” caused by natural food ingredients.

The same types of effects that are produced by exposure to natural chemicals, such as carcinogenicity and hormonal effects, also can occur from exposure to synthetic chemicals. In almost all cases, these effects occur only at high doses and so, as a group, synthetic chemicals are no more toxic than natural ones. The potency of a chemical does not depend on whether it is natural or synthetic; some of the most toxic chemicals are natural and some of the least toxic are synthetic. Indeed, there are a number of natural chemicals that are very highly toxic; these include the toxins that cause botulism and tetanus.

Both synthetic and natural chemicals can be toxic and present risks. Whether a chemical should or should not be used should be based on its risks and benefits, and how or if it should be used. For example, a synthetic chemical used as a pesticide may be very important for destroying insects that carry dangerous diseases but may also cause toxicity at high doses. Chemicals naturally occurring in gasoline, a product critical for transportation, may also cause toxicity if exposures are high. In both cases, these chemicals are valuable because their benefits outweigh their risks.

Myth #3: Synthetic chemicals are the cause for the rising incidence of many serious diseases, including cancer

First, over the past few decades there has been a decrease, not an increase, in the rate at which new cancers are diagnosed and the rate at which people die from cancer. Second, while there have been reported increases in the incidence of other diseases, the causes for such increases are not known.

Cancer is a disease that causes dread because of the toll it takes on victims and their families.

Because cancer is a disease that becomes more common as we age, the number of cancers has been increasing as we live longer. This increase in number gives the perception that cancer is becoming more common at all ages. However, when the incidence and death rates for cancers are calculated for each age group, it can be seen that they are decreasing. For example, if we looked at the rate of cancer in 80 year olds today, we would find that it is lower than it was in 80 year olds 10 years ago.

Cancer is not the only health problem that is of serious concern. Diseases that affect children, such as autism and asthma, also have been in the public eye because of reported increases in the numbers of cases of these illnesses. Careful studies of the reasons for these increases suggest that in many cases they are apparent, not real. This can occur due to changes in diagnostic practices, greater availability of diagnostic and treatment services, earlier age at diagnosis, and greater public awareness. The scientific evidence does not support claims that these diseases are due to chemical exposures.

Further, when overall health indicators—rather than the incidence of individual diseases — are examined, it is clear that the health of the American population has been continually improving. Longevity has increased significantly during the last 50 years, a period marked by a tremendous increase in the types and amounts of chemicals in everyday use. In addition, people are staying healthy longer, so that the quality of life as well as our average lifespan has improved in recent generations.

Thus, the myth that there has been a rising incidence of serious illnesses and that these are due to the increased use of synthetic chemicals does not stand up to scrutiny. It is very clear that public

health has improved significantly over the recent past, due in large part to the contributions of synthetic chemicals to the diagnosis and treatment of a wide variety of diseases. Careful analysis reveals that many claimed increases in diseases are not real. In addition, in-depth assessments of the causes of existing cases of these illnesses do not demonstrate a connection between the diseases and environmental chemicals.

Myth #4: Detection of a chemical in the environment or a sample of blood or urine means that people are in danger of adverse effects.

People are exposed to thousands of natural and synthetic chemicals each day without evidence of harm. Thus, the detection of a chemical in the environment or in a sample of blood does not imply that toxic effects are occurring.

Because natural and synthetic chemicals occur in the environment around us, people are exposed to these agents each day in the air they breathe, the water they drink and the food they eat.

Therefore, it is not surprising that these chemicals can be found in samples of human blood and/or urine. Indeed, reports about the variety of chemicals found in such samples are common in the media. In some cases, reporters have written stories on analyses of their own blood or urine to dramatize the findings. In other instances, reports feature the results of large-scale government studies on the blood and/or urine levels of environmental chemicals.

What does the discovery of these chemicals in human fluids mean? First, human blood and urine normally contain a wide variety of natural chemicals. Blood contains nutrients that are carried throughout the body, but it also transports unwanted waste products resulting from normal body processing of these nutrients. These products go to the kidneys where they are excreted in urine.

Many of these waste compounds can cause serious effects in people if they build up to high levels as can happen when the kidneys do not function properly.

Similarly, a number of environmental chemicals, both natural and synthetic, can be found in the blood and urine. The human body has the ability to excrete these just as it excretes its own unwanted waste products. The presence of such chemicals does not imply that any adverse effects are occurring, just as the presence of the body's waste products does not mean that the humans carrying them are suffering toxicity. Only if these environmental chemicals build up to high levels is there a likelihood of harm.

Careful analysis by government scientists of the levels of these environmental chemicals in blood and/or urine demonstrates that they are almost always present at very low levels, often called trace levels. These levels are not high enough to cause any harm; just because they are present does not mean that there is a risk involved. These analyses tell us only if people have been exposed to the chemicals studied — not if any effects are likely. Additional information, such as how often exposure has occurred, for how long and at what levels, is necessary to determine the possibility of toxic effects

Myth #5: Chemicals used in food, consumer products and agriculture have not been shown to be safe.

Since all chemicals, natural or synthetic, can cause toxicity at some dose, none of them are absolutely safe. Indeed, there is no way to show that any chemical is absolutely safe at any dose since you can always imagine other tests that could be performed to look for more and more obscure and unlikely effects.

Since absolute safety is not a possibility, the question is whether these food, consumer and agricultural chemicals have undergone enough testing so there is a reasonable likelihood that they will cause no harm when used properly. While it has been claimed that adequate testing and evaluation have not been performed—and thus that our food and consumer products are unsafe—a careful analysis shows that this is not the case.

The claims of insufficient testing are of two types. The first is based on the idea that the current toxicity tests are not appropriate in the light of new knowledge. A good example of this is the assertion that chemicals can show no effects at high doses but still produce significant toxicity at much lower doses. Those who espouse this view say it demonstrates that traditional testing done at high doses may miss toxic effects. That's a controversial hypothesis that has, as yet, limited support among scientists.

The second type of claim is that not enough testing has been done or that it has been performed and/or evaluated in a biased way. Generally, the incomplete or biased testing results are linked to industry. While it is true that much of the toxicity testing of products in commerce is performed by industry, this is because the federal regulatory system requires such evaluations. This approach has been very successful in almost all cases, as evidenced by the overall safety of the food supply and the very small number of chemicals in consumer products that have been shown to cause any toxicity, even in sensitive individuals, when used as intended.

Thus, the belief that chemicals have not been adequately tested before the public is exposed to them does not hold up under careful scrutiny. It is based on two assertions, neither of which is supported by the evidence. The first, that current test methods are inadequate, is based on

assertions of scientists who do not represent the scientific consensus and the second, that industry testing is insufficient and/or biased, is not supported by the safety records of foods and consumer products.

Myth #6: If there is any evidence that a chemical might cause harm, it should be taken off the market.

As stated previously, all chemicals, both natural and synthetic, are toxic at some exposure level so applying this principle would lead to the removal of all chemicals, whether beneficial or not. This approach would deny people the benefits of drugs that cure serious diseases, disinfectants that protect citizens against microorganisms, pesticides that protect us against insect-borne diseases, and a host of lifesaving medical devices.

Those who believe that chemicals should be removed from the market whenever there is the slightest evidence that they may cause harm base this view on the “better safe than sorry” precautionary principle. However reasonable this principle may seem on the surface, this approach is unlikely to make you safer and, instead, could very well increase risk.

Why is this? For one, devoting resources to taking a chemical — and products containing it — off the market and replacing it means that these same resources will not be available to assess other risks. If there is little evidence that this product causes serious harm, then it is unlikely there will be any reduction in risk from removing it. On the contrary, since this action would divert resources from known risks to public health, it is more likely that there would be a net decrease in safety.

In addition, the replacement of a product in common use has environmental consequences since

it would require the use of significant amounts of energy to collect and dispose of the banned substance, and to develop, produce, market and distribute a replacement. Generating the energy needed for these steps would be associated with pollution and the potential for adverse effects in people exposed to these pollutants. Thus the replacement process itself entails risks that must be considered.

It is often the case that at least some of the benefits of the product being replaced are lost. This happens because many products, such as plastics in medical devices, are in use because of unique properties that cannot be exactly duplicated. Thus, in addition to a significant possibility of increased risk from banning a chemical of unproven harm, there is also the likelihood of a loss of benefits.

Because all chemicals are toxic, it is quite likely that there will be some toxicity associated with the replacement. It is often not clear until a product has been in use for a long time what this toxicity is and how many people it may affect. It is quite possible that the replacement chemical, and products containing it, will be associated with at least as much risk as the original chemical. The application of the principle of “better safe than sorry” can result in the replacement of an unsubstantiated risk with an unknown one.

The seemingly prudent step of taking chemicals off the market when there is the slightest suggestion of toxicity is unlikely to accomplish what is intended. Because there is no solid evidence of harm, it is not clear that any reduction in risk will occur. It is much more likely that there will be an overall increase in risk, because the substitution process incurs other risks, as well as a loss of benefits if the chemical and products containing this chemical are taken off the

market. The really prudent step is to make the best scientific evaluation of the risk from the product as compared to the risks and loss of benefits associated with removing it from the market before any actions are taken.

Myth #7: Claims by advocacy groups are objective and based on the best science.

Although advocacy groups often assert that their claims of danger from chemicals are based on science, close examination reveals that these assertions often do not reflect the best or most complete science. In some cases, they do not reflect any science at all; they rely on the belief that the presence of a chemical is equivalent to risk.

Advocacy groups, as their name implies, advocate for particular positions. In the process, they marshal the best arguments they can make to support their position. This often entails citing evidence that is most conducive to their case, no matter how valid, and ignoring evidence that is contrary to it. Further, they often try to portray scientists who have an opposing view as biased while asserting that they are objective. Relying on the tendency of many media sources to publicize dramatic findings, they are often able to dominate the headlines.

However, a close scientific examination of advocacy group claims reveals they are often based on studies by scientists who do not reflect the expert consensus or a balanced treatment of the available evidence. Instead, they tend to emphasize the worst possible interpretation of the data. Yet, in the absence of solid evidence, such groups suggest that restricting or eliminating particular chemicals is necessary. This position is based on the conviction that it is prudent to take chemicals off the market even if there is only the slightest support for the contention that they pose a risk to the public.

Unfortunately, a number of factors contribute to the public's willingness to accept blanket claims by advocacy groups. The media give excessive attention to the views of NGOs that are sensational and critical of industry. Industry responds to the barrage of negative publicity by removing the attacked products. That often leads government officials to pass restrictive legislation. This attack and withdraw cycle, repeated again and again, contributes to a public perception that the original allegations were scientifically valid. However, this is often not the case. These predictable reactions by the media, industry and government are shaped by the desire for publicity at any cost, or by policy and economic considerations, not on an assessment of the scientific validity of the claims.

Yes, environmental disasters have occurred due to corporate greed or indifference and government incompetence. There are examples in which corporations have exercised their influence to bend policy to their needs, and the public has paid the price. But for the most part, the desires of corporations and the public coincide. Businesses that break the trust of their customers don't prosper let alone survive. And in all but a very few instances, the regulatory machinery, however inefficient, does identify new drugs, improved ways to grow and preserve foods, and enhance the quality of our food and water. We can improve the system, in some cases significantly, but the evidence doesn't support the cynical belief encouraged by many activists that corporations are out to fleece their customers and government is corrupt or hopelessly inefficient.

Science needs to rest on a solid body of independently verified evidence. Any evidence is not equivalent to valid evidence. When scrutinized, many claims by advocacy groups are not scientifically sound. They reflect a selective use of facts and often rely on scientists with a

demonstrable (and sometimes avowed) bias. These groups often rely on popular but mistaken beliefs to bolster their positions: that it is possible to have chemical-free products; that synthetic chemicals are more dangerous than natural ones; that some chemicals are nontoxic; that synthetic chemicals are responsible for increases in disease; that detection of a chemical is equivalent to a toxic effect; and that it is prudent to take useful and desirable products off the market even in the absence of solid scientific evidence of harm. That's not science.

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Grice, Joshua (ECY)

From: Daniel Simmons [dsimmons@energydc.org]
Sent: Wednesday, June 15, 2011 12:57 PM
To: Williams, John (ECY)
Subject: Comment on the proposed listing of phthalates under Children's Safe Products Act
Attachments: American Energy Alliance on phthalate listing.pdf

Mr. Williams,

Attached please find a comment from the American Energy Alliance on the proposed listing of phthalates as chemicals of high concern under the Children's Safe Products Act.

Daniel Simmons
Director of Regulatory and State Affairs
American Energy Alliance
202-621-2954



John R. Williams
Washington State Department of Ecology
PO Box 4760
Olympia, WA 98504-7600

Dear Mr. John Williams:

I am writing to express concern with the Department of Ecology's proposed listing of six phthalates as chemicals of high concern to children under the Children's Safe Products Act. Listing phthalates as chemicals of concern to children has far reaching implications for the economy as well as consumer safety.

Over recent years, various environmental activists have targeted this family of chemicals as a part of their all-encompassing calls for increased chemical regulation across government. However, the truth is that the cries for regulation are often used as a justification to attack the private sector and are not supported by any scientific evidence. Listing phthalates as chemicals of high concern for children is not justified when you look at the science. For decades, phthalates have been used as plasticizing substances to make plastics soft and flexible. Phthalates are the most widely used plasticizer due to their effectiveness and durability. Because of their widespread use, scientists have thoroughly studied their toxicological profiles and phthalates remain one of the most studied substances in the marketplace. Government agencies here in the European Union and United States – including the Consumer Product Safety Commission, the National Toxicology Program and the EU Chemicals Bureau – have taken the lead on vetting these substances for use and deemed them safe for intended uses.

The fact that phthalates are regulated by the federal government is not an indication of a Congressional determination that these phthalates pose a risk to human health when used in children's products. In fact, it was the result of a political decision rather than a scientific one. The long lead up to this baseless inclusion dates back to an amendment introduced by Senator Feinstein of California, who pushed for a federal phthalate ban only because California had enacted a ban in 2007. That California legislation was passed in order to mirror European legislation. As you may know, legislation in Europe is based on the precautionary principle (i.e. chemicals are considered dangerous until proven otherwise) and political pressure resulted in the inclusion of phthalates even though comprehensive European risk assessments concluded there was no concern.

Listing phthalates would have adverse economic effects including sending a signal to manufacturers to move away from using phthalates in consumer products, thus leading to the substitution of alternative plasticizers which do not carry the same safety record as phthalates. Substitution of alternatives could lead to less effective alternatives that could pose potential safety concerns as well as lead to products that are of an inferior quality putting Washington business at a competitive disadvantage.

Phthalates are an important part of the plastics industry in Washington and listing phthalates could lead to a subsequent decline in the state's economic health and fiscal well-being. Across the state of Washington, the manufacturing and production of plastics is a multi-million dollar industry. According to the Society of Plastics, the industry stimulates more than \$628 million on an annual basis and over \$5 billion in state payroll taxes and federal taxes paid by companies in the plastic industry and those that depend on it. How about jobs? Regulating phthalates would jeopardize some of the more than half a million jobs that are associated with the State of Washington's plastics industry. Considering that thousands of state residents are still desperate to find work, one would assume that state officials would realize the potentially crippling effects an attack on phthalates could cause to local job numbers.

In addition to the economic fallout, listing phthalates as chemicals of concern to children would conflict with existing federal law, the Consumer Product Safety Improvement Act from 2008. The CPSIA explicitly mandates pre-emption of any state or local law that is inconsistent with the phthalates provisions. As provided for under the CPSIA, if either the statutory ban it establishes or any other regulations regarding the hazards that the CPSC issues under the authority which it provides for, neither a state nor municipality may "establish or continue a requirement applicable to such substance designed to protect against the same risk, illness or injury unless the requirement is identical to the federal requirement." With the federal law already on the books, the proposed listing would face immediate legal challenges which would be a waste of time and resources at a time when the state is already financially strapped with a budget deficit.

Washingtonians, like all Americans, expect regulatory programs to keep them safe. Imprudent and ill-advised rules, such as a listing of phthalates, are not the way to achieve this goal. Washington State must create a regulatory framework that is informed by scientific evidence and does not use a large brush to paint all chemicals as detrimental to human health. If we do so, the safe ones will be unnecessarily stigmatized, enterprise will suffer, and your state's resident will be subject to the increased risks.

For the reasons above, I believe it would be in the interest of public health and the state's economy to remove phthalates from the listing rule.

Sincerely,



Daniel R. Simmons
American Energy Alliance
Director of Regulatory and State Affairs

Grice, Joshua (ECY)

From: Darlene St. Martin [stmartin79@comcast.net]
Sent: Monday, June 13, 2011 7:58 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Darlene St. Martin
506 N Laventure Road
Mount Vernon, WA 98273

Grice, Joshua (ECY)

From: Pam Utz [Pam_Utz@gap.com]
Sent: Wednesday, June 15, 2011 10:45 PM
To: Williams, John (ECY)
Cc: Kraege, Carol P. (ECY); Sean_Cady@vfc.com; Frazier, John; Pidgeon, Elena; Man, Kitty; Goldman, Laurie; Nathaniel Sponsler
Subject: RE: WA CSPA - Reporting Rule Comments - June 15, 2011 (Gap, Levi, Nike, VF)
Attachments: WA CSPA Reporting Rule 6-15-11 Final.pdf

Dear John,

Thank you for the opportunity to comment once again on the Reporting Rule under Washington's CSPA. We appreciate your consideration of industry input on how to achieve the State's objectives. Attached is the joint response of Gap Inc., Levi Strauss & Co, Nike Inc, and VF Services, Inc.

Please let us know if you have any questions.

Cordially,

Pam Utz, Director, Product Regulations, Gap Inc.
Nathaniel Sponsler, Manager, Product Regulations, Gap Inc.

Elena Pidgeon, Senior Manager, Product Safety LS Americas, Levi Strauss & Co.
Kitty Man, Ph.D., Global Leader, Restricted Substances, Levi Strauss & Co.

John Frazier, Director of Sustainable Chemistry and Water, Sustainable Business and Innovation, Nike Inc.

Sean Cady, Vice President, Product Stewardship and Sustainability, VF Services, Inc.

June 15, 2011

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: Reporting Rule

Dear John,

Thank you for the opportunity to comment on the May 4, 2011, revision of the CSPA Reporting Rule (Chapter 173-334 WAC). We appreciate your willingness to engage with us as stakeholders in many contacts over the past year, resulting in three comments to date (Oct.1, Dec. 22, 2010, Feb. 15, 2011). The new elements in the latest version of the Rule prompt an additional comment.

In summary, we have long-established policies and practices in place at our respective companies that ensure the safety of all our products. Our practices are based on a combination of compliance with global legal requirements, established industry product safety standards, our internal risk assessment, and verification systems such as factory audits and product testing. We have found this combination of efforts successful in ensuring that only safe products are produced and sold by our companies. On the other hand, as discussed below, the product testing requirements implicit in the CSPA Reporting Rule do not enhance the safety of children's products. Moreover, requiring companies to expend significant resources simply to determine if any amount of a substance, no matter how minute, is present in the product takes away from the working programs already in place at our companies.

1. CSPA is a reporting law.

The stated goal of CSPA and the Draft Reporting Rule is information gathering. Most Washington retailer-importers, who are responsible for reporting when the manufacturer resides outside the state, must rely on information from their suppliers to fulfill this obligation. They will do this primarily through Material Safety Data sheets (MSDS) prepared by chemical manufacturers which in large part do NOT provide data to the levels required for CSPA. The result is that although CSPA does not mandate testing of children's products to determine concentrations of listed Chemicals of High Concern, as currently written the law would impose a substantial new cost burden on retailers and importers in the State. We do not believe that this has been weighed by legislators nor figured into administrative reviews. This additional testing cost to supply chains both inside and outside of Washington State diverts resources from due diligence activities that companies with a managed Restricted Substances List perform as part and parcel of their manufacturing control programs.

We also believe that the new draft regulation moves beyond the stated goal when it institutes the "PQL"--Practical Quantification Limit¹ in analytical testing--as the trigger for reporting. To support this,

¹ " 'PQL Practical quantification limit' (PQL) means 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. The value for a given chemical could be different depending on the matrix and the analytical method used." (Definitions WAC 173-334-040)

retailer-importers would need to rely heavily on sophisticated laboratory testing to detect 66 and more substances across all children's products. Although we share the goal of strong product stewardship, we do not believe the current approach offered by the rule results in safer product.

In addition to being costly, many of the listed Chemicals of High Concern in the Reporting Rule have no validated test methods for the materials and components used in our industry. Laboratories as well as standard-making bodies do not agree on methods or they modify them individually, which means there will be different PQLs for the same substance. In fact the definition of PQL (footnote 1) makes clear that this trigger level for reporting need not be the same for two importers bringing in an identical product but using different laboratories with different methods and equipment variables. The ensuing difficulties both for compliance and enforcement can be avoided if the trigger for reporting followed the broadly accepted standard for "no effect" used on Material Data Safety Sheets and in regulations like the European REACH (1000 ppm). In any case, companies who invest in testing programs follow test methods with PQLs appropriate to materials in their industry. We suggest that Washington consider the use of established test methods and associated detection levels already applicable to the specified product.

2. "Intentionally added"² substances perform a function in the finished product.

We support in principle the new approach of distinguishing between intentionally-added chemicals and contaminants as established in section 173-334-080 (1). By focusing on those substances purposely added to perform a specific function in finished products, we believe Ecology will collect more meaningful data and help focus agency attention and resources.

However, the new concept of the intentionally-added chemical adds a level of complexity and judgment to reporting. Almost all apparel and footwear products consist of formulations of multiple chemical substances. In textile products, many of these formulations assist early in the manufacturing process, for example, to make a fabric able to accept dye. Although intentionally used, such chemicals are not intended to remain on the fabric or garment as each passes through subsequent processes later in manufacturing. Nor are these substances intended to impart a function or effect in the finished product. By comparison other chemical formulations are intended to persist in the component and perform functions in the product, such as wrinkle-resistance finishes on fabric.

Properly classifying which substances are intended to perform a function in the finished product as opposed to assisting earlier in the manufacturing process requires expert knowledge, and grey areas exist where professional interpretations may conflict. We ask that Ecology carefully consider this reality and defer to manufacturer expertise in differentiating between the two types of substances where there is uncertainty. We believe that only those substances required to be present in the final consumer product to impart a desired function should be covered by the "intentionally added" definition.

In this context it is also important to point out that the Reporting Rule, in trying to define "product component"³, departs from the prevailing standard in other laws: A component is that which can be

² "'Intentionally added chemical' means a chemical in a product that serves an intended function in the product component." (Definitions WAC 173-334-040)

³ "'Product component' means a uniquely identifiable material or coating (including ink or dye) that is intended to be included as a part of a finished children's product." (Definitions WAC 173-334-040)

physically separated from another. Thus a reactive dye, for example, once applied and reacted on the fabric, is not a component because it can no longer be separated from the fabric and analyzed on its own. A coating in contrast can be removed and analyzed. We suggest that Ecology maintain the more standard definition of a product component.

3. Restricted Substances List (RSL) Testing Program is a Manufacturing Control Program

We support the rule changes that acknowledge our and others' commitment to product safety by virtue of effective chemical control policies and practices. The new subsection WAC 173-334-080 (1)(c) states that a "manufacturer need not file a notice with respect to any CHCC that occurs in a product component only as a contaminant if the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component."

We believe this approach promotes responsible chemical management by largely exempting those manufacturers from notification who invest significant resources into Restricted Substances List (RSL) testing programs. We are confident that our respective programs work to effectively minimize the presence of many of the listed substances where they can occur as unintended contaminants of the manufacturing process. We further believe this provision will encourage other footwear and apparel companies to develop robust RSL programs of their own, a key objective of the AFIRM⁴ Group, which we are all members of.

Thank you 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, Manager, Product Regulations, Gap Inc.

Gap Inc.

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.



⁴ www.afirm-group.com

Sean Cady, Vice President, Product Stewardship and Sustainability, VF Services, Inc.



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 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.

About VF

VF Corporation is a global leader in branded lifestyle apparel with more than 30 brands, including *Wrangler(R)*, *The North Face(R)*, *Lee(R)*, *Vans(R)*, *Nautica(R)*, *7 For All Mankind(R)*, *Eagle Creek(R)*, *Eastpak(R)*, *Ella Moss(R)*, *JanSport(R)*, *lucy(R)*, *John Varvatos(R)*, *Kipling(R)*, *Majestic(R)*, *Napapijri(R)*, *Red Kap(R)*, *Reef(R)*, *Riders(R)* and *Splendid(R)*. VF Corporation's press releases, annual report and other information can be accessed through the Company's home page, www.vfc.com.

Grice, Joshua (ECY)

From: Laurie Valeriano [lvaleriano@watoxics.org]
Sent: Thursday, June 09, 2011 5:02 PM
To: Williams, John (ECY)
Cc: Fritz, Angela (ECY); Kraege, Carol P. (ECY)
Subject: Re: CSPA testimony
Attachments: Rulecommentsoral.docx; ATT1913921.htm

John, here is my oral testimony..

I have to take the pics tomorrow. Thanks, laurie

**Public Comments of
Laurie Valeriano, Policy Director, WA Toxics Coalition on the
Children's Safe Products Act Rule
Public Hearing on June 8, 2011**

Thank you. We appreciate the opportunity to provide comments on this important rule.

Washington Children's Safe Products Act is a critical groundbreaking law that can help fill major gaps we have about where harmful chemicals may be lurking in products that our kids use everyday – from toys and tween lotions and perfumes to car seats and bedding.

We already know that the problem is much greater than lead in toy trains, which is what sparked this issue in 2007.

And we know that the federal Toxics Substances Control Act does not require basic health or safety testing on chemicals before they are put into products.

Whether it was baby bottles made with bisphenol A, phthalates in vinyl toys, cadmium in shrek glasses or toxic flame retardants in baby products, we know no one is minding the store when it comes to chemical regulation and it is virtually impossible for consumers right now to figure out where harmful chemicals are used. As a person working on these issues for 2 decades, I can't even figure it out sometimes.

It's really up to the states to step in and protect children and families from harmful chemicals right now and this law needs to be implemented in a way that gets the right information into the hands of consumers and government so that they can take the appropriate action – whether it is, for consumers, avoiding the purchase of products with harmful chemicals or for government, restricting the use of chemicals when safer alternatives exist.

We want to thank the department for the following changes to the rule from the last version, including:

- Eliminating the 40 ppm and going to the “intentionally added” language.
- Clarifying the intent of the agency to put the information on the web site as resources allow.
- Adding phthalates to the list of Chemicals of High Concern for Children.

Specific Product Information

Our biggest concern in this current rule draft is that the agency is not carrying out the law and its intent when it comes to getting product specific information.

The basic requirement in the law is simple. Every year, manufacturers of children’s products submit a report if their product contains a chemical of high concern for children that is on the list. This information is needed for two reasons:

- Government needs to be able to assess the extent to which harmful chemicals are used and how children may be exposed; and,
- Absent strong protections in place to prevent the use of harmful chemicals in kids products, it is critical consumers have this information so they can make the best choices for their families.

The problem is that the rule only requires manufacturers to report the amount of the chemical in product categories. There are several problems with this approach.

1) Consumers will remain in the dark.

For example, companies that make perfume can keep secret their use of toxic chemicals by using the word “fragrance” on the list of

ingredients. Phthalates can often be used as fragrance additives. In this product, “Britney Spears, Curious” we know from testing done by the Environmental Working Group, that there is Diethyl Phthalate, which is an endocrine disrupting chemical on the CHCC.

According to the rule, Elizabeth Arden would only have to report that they use DEP in fragrance (brick level) and the amount in a range that the chemical is present in their product. This information is not enough to provide consumers or the government with the ability to make decisions.

We already know in general that DEP is used in fragrances, but we need to know where specifically it is and how much if there aren't going to be protective standards that protect our children from hormone disrupting chemicals.

2) It will be difficult for the agencies – Ecology and Health – to assess the extent to which the chemicals are used in particular products and what the potential concerns may be. For example, the agencies won't know that Company X uses DEP in 1 product where only 100,000 units were offered for sale in Washington or if Company x used DEP in 100 products where 100 million units were offered for sale and that all together there are 10 companies that use DEP in 1000 products where 600 million product units were offered for sale. While we would say in general that it is better to get DEP out of all fragrances, agencies need to prioritize resources and figure out where to focus their attention so they need the right information to do this.

3) The Department of Health won't be able to carry out an effective public education campaign on chemicals of high concern for children in children's products, as required under the law if they don't have more specific information about the products that the chemicals are in and the extent to which kids may be exposed to these products.

We can understand and appreciate the complexity and the volume of information that obtaining this level of data may pose, however,

there could be additional levels/tiers put in place to be able to manage the data that is submitted. For example, Ecology could call in data for all flame retardants, then plasticizers, fragrances, then inks/dyes, etc..as a way to stagger the inflow of data. From a data assessment perspective, this approach also makes it easier because you would also be looking at the function of chemicals by category.

Again, this information is critical in the absence of federal TSCA reform and a lack of authority at the state level to ban and restrict harmful chemicals in children's products that goes beyond, lead, cadmium and phthalates.

Additions to the List

The list is strong and we appreciate all of the hard work that has gone into it from DOH, UW and Ecology. Again, we thank you for the additions of the phthalates and for keeping cadmium on the list.

In light of the new data that came out recently on toxic flame retardants in baby products, we ask that two specific FRs be considered for the list.

Tris(1,3-dichloroisopropyl)phosphate, also known as TDCPP or chlorinated Tris, CAS # 13674-87-8

- considered probable human carcinogen by CPSC
- found in 29 of 101 baby products tested
- found in 96% of house dust tested, 50 Boston homes (Stapleton 2009, ES & T)

2-ethylhexyl-2,3,4,5-tetrabromobenzoate, also known as TBPH, CAS #26040-51-7

- found in 17% of baby products tested
- found in 100% of house dust tested, 19 Boston homes (Stapleton 2008, ES & T)
- EPA structure activity for eco-toxicity.

Loopholes

Finally, we are concerned about two loopholes in the rules.

- 1) The addition of “mouthable” to the products that will be dealt with first. The rule, last go around, put all products for kids 3 and under in the first reporting tier, which meant that the largest companies that made these products would report first. This made sense. Adding the phrase “mouthable” to the children’s products for kids three and under makes it confusing and also not realistic. Most everything intended for kids 3 and under are mouthed by children that age. A baby blanket for infants will spend a lot of time in a child’s mouth but it doesn’t clearly meet the definition, which is “means able to be brought to the mouth by a child so it can be sucked and chewed”. It just makes it an arguable point for a manufacturer of a baby blanket that has formaldehyde in it, and it shouldn’t be a question. Infant products, should be a priority for reporting first because of their vulnerable stage of development.

- 2) The reporting for contaminants is also a concern for us. Both for enforcement and for the ability of manufactures to claim that the chemical in their product is a contaminant, not intentionally added.

At the very minimum, incompletely reacted components and degradation products should be removed from the definition of contaminants.

Manufactures could argue that incompletely reaction components could include things like like styrene in ABS, but we would argue that styrene, a carcinogen should be reported in this case because the

manufacture is choosing to use this kind of plastic that has a certain characteristic for it's product.

And, manufactures could also argue that degradation products include fluorinated polymers where the residual can degrade into PFOA. These chemicals are being chosen for their particular function in the polymer and are highly persistent and toxic and should not be allowed to escape thru loopholes.

Thank you for your work on this important rule and the opportunity to provide these comments.

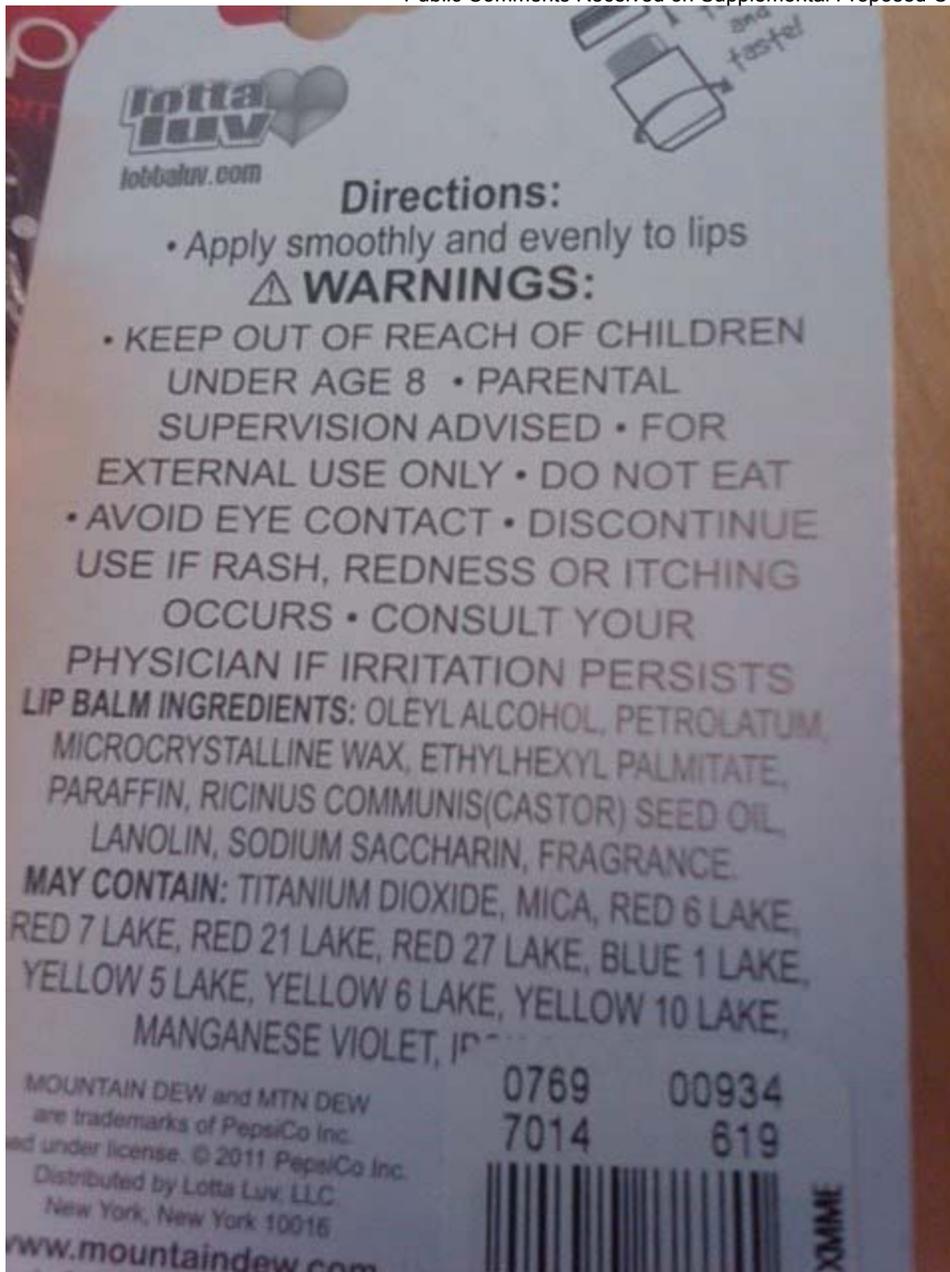
Grice, Joshua (ECY)

From: Laurie Valeriano [lvaleriano@watoxics.org]
Sent: Monday, June 13, 2011 3:16 PM
To: Williams, John (ECY)
Cc: Fritz, Angela (ECY)
Subject: Re: CSPA testimony

Here is a pic of the props I used:

- 1) Britney Spears, Curious perfume as referenced in the oral testimony.
- 2) Mouth light-up piece purchased by my daughter had lead internal parts that were measured with an XRF analyzer.
- 3) Lip balm examples.
- 4) Second picture is the warning label on the lip balms.





On Jun 9, 2011, at 1:23 PM, Williams, John (ECY) wrote:

Hi Laurie –

When you email me your testimony, could you also include photos of your ‘props’ or at a minimum a written description – We need them for the public record.

Thank-you

John

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

360/407-6940
FAX 360/407-6102

jowi461@ecy.wa.gov

Π Please consider the environment before printing this e-mail

Laurie Valeriano
Policy Director
WA Toxics Coalition
4649 Sunnyside Ave. N, Suite 540
Seattle WA 98103
206-632-1545x114
lvaleriano@watoxics.org

Grice, Joshua (ECY)

From: Johari Vos [jo@jovos.com]
Sent: Monday, June 13, 2011 5:49 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Johari Vos
6310 19th Ave. NE
Seattle, WA 98115

Grice, Joshua (ECY)

From: Mare Wahosi [one2onestars@yahoo.com]
Sent: Tuesday, June 14, 2011 12:10 AM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Mare Wahosi
840 Retsil Ave East
Port Orchard, WA 98366

Grice, Joshua (ECY)

From: Blanco, Susan [Susan_Blanco@americanchemistry.com] on behalf of Walls, Michael [Michael_Walls@americanchemistry.com]
Sent: Wednesday, June 15, 2011 11:27 AM
To: Williams, John (ECY)
Subject: Comments from the American Chemistry Council
Attachments: 061511 ACC WA CSP Comments.pdf

Attached please find comments from the American Chemistry Council on the Department of Ecology's (Ecology) WAC § 173-334, proposed regulations to implement the Children's Safe Products Act – Reporting Rule.

Thank you for the opportunity to comment. If you have any questions, please contact me or Emily Kolarik (emily_kolarik@americanchemistry.com; 202-249-6127).

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MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

June 15, 2011

SENT VIA ELECTRONIC MAIL

Mr. John R. Williams, Jr.
Washington State Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600
john.williams@ecy.wa.gov

Dear Mr. Williams:

The American Chemistry Council (ACC) appreciates the opportunity to comment on the Department of Ecology's (Ecology) WAC § 173-334, proposed regulations to implement the Children's Safe Products Act – Reporting Rule.¹ As ACC has stated in the past, 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. ACC continues to support several provisions in the proposed regulations, including a few of the newly proposed concepts. However, there are several provisions that cause significant concern.

Presence Does Not Equate to Harm

ACC commends Ecology for noting in the introduction (WAC § 173-334-010) that “the presence of a chemical of high concern to children (CHCC) in a children's product does not necessarily mean that the product is harmful to human health or that there is any violation of existing safety standards or laws.” The CHCC list is not a list of chemicals that pose an unreasonable risk of harm. Small amounts of chemicals that may be identified as CHCC are added to things like coatings, and plastics, for example, to provide a safety benefit such as to improve stability. The improved stability may result in lower exposures to other chemicals present, and, improved stability may extend the life of a product, so they do not end up being disposed of prematurely with downstream releases of other ingredients.

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.



It remains unclear as to how the purpose of the list will be communicated to the public or more specifically, consumers of children's products once the regulation is made final. In ACC's view, it remains essential that whenever Ecology publishes, references or identifies the CHCC list or the presence of CHCC substances in products, that Ecology carefully do so in context. The regulations should require an appropriate notice/explanation on all department publications, brochures, websites, public notices, compliance documents, and media releases in a prominent and easily understood manner so that consumers can clearly comprehend the meaning of this list.

Without clear direction from Ecology that the presence of CHCCs in products does not establish that a product is harmful to human health, the public will be confused as to what the CHCC list truly is, and what it is not. More importantly, the absence of such notice will exacerbate market effects for all noticed products, as consumers may understand the listing to be a regulatory decision that a product poses the risk of harm. Inevitably 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's shelves.

In sum, Ecology must take steps to communicate clearly what the CHCC list is, and, more importantly, what it is not. This clarification is essential to minimize premature product de-selection by consumers, retailers, and suppliers. If not, the CHCC list becomes a blacklist by default. Ecology's proposed regulations, as written, could cause confusion for consumers, could negatively impact the market and as a consequence may not serve the public health interests of the citizens of Washington.

ACC continues to urge Ecology to define "presence of a substance" in the final regulations to mean presence above thresholds at which there may be exposures that would pose a risk of harm. In WAC § 173-334-070, Ecology clarifies that it will identify chemicals for inclusion on its list of CHCCs by determining whether a chemical meets both toxicity, persistence, or bioaccumulation criteria *and* meets exposure criteria specified in the authorizing legislation.

ACC appreciates Ecology's recognition that the regulatory program must integrate hazard and exposure information to identify CHCCs. A robust prioritization process, which is necessary to identify and prioritize chemicals in commerce that pose the greatest concern, should utilize specific hazard and use/exposure criteria so that both governmental and industry resources are directed toward the greatest potential risks. In the absence of prioritization, everything (or nothing) is a priority, a result that has serious implications for the effective management of any regulatory system.

For any chemical, natural or synthetic, the degree of toxicity and the potential for harm is dependent upon the dose/exposure. Federal government agencies, including the U.S. Environmental Protection Agency (EPA) and the Centers for Disease Control readily acknowledge that the mere presence of a substance in the environment, in our bodies, or in our products, does not equate to the risk of harm.² To enact regulation that is scientifically justifiable

² Centers for Disease Control and Prevention, National Health & Nutrition Examination Study's (NHANES) National Report on Human Exposure to Environmental Chemicals: Introduction (Feb. 2011), available at http://www.cdc.gov/exposurereport/data_tables/introduction.html. The NHANES Report is referenced by EPA

and that makes clear public health sense, ACC urges Ecology to define “presence of a substance” in the final regulations to mean presence above a threshold or de minimis level.

Additional Exemptions to RCW § 70.240.010

ACC appreciates the exemptions addressed in WAC § 173-334-040(b), referring to the statute’s definition, stating that “children’s product’ does not include over the counter drugs, prescription drugs, food, dietary supplements, packaging, medical devices, or products that are both a cosmetic and a drug regulated by the Food and Drug Administration” (FDA). To further clarify, Ecology should explicitly include additional mention of federal programs that already regulate products in Washington, and are thus not subject to Ecology’s proposed regulations. These include products regulated under the: Consumer Product Safety Improvement Act; Toxic Substances Control Act; and Federal Insecticide and Fungicide and Rodenticide Act.

The regulation should also exempt internal components of products that are not likely to come into contact with children through reasonable and foreseeable means, as referenced in WAC § 173-334-110(4)(d). Such an exemption is consistent with the objective of focusing on those products which pose an actual risk of exposure to children.

De Minimis and PQL

Proposed WAC § 173-334-080 would require the annual notice to disclose each listed CHCC that is (a) intentionally added to a children’s product at any concentration above the practical quantification limit (PQL), and (b) each CHCC that is a contaminant in a children’s product at any concentration > 100 ppm, unless (c) the manufacturer has in place a control program and exercised due diligence to minimize the presence of the contaminant. This information would be available for public disclosure unless Ecology accepted the submitter’s claim that some of the information should be treated as confidential business information. While ACC agrees with the addition of the manufacturer due diligence clause, the proposed requirements, such as the PQL, are unnecessary and go well beyond the intent of the Children’s Safe Products Act (CSPA).

1. Disclosure of Intentionally Added Components

While ACC appreciates Ecology distinguishing between “contaminant” and “intentionally added chemical,” the proposed threshold for reporting intentionally added components is unnecessary and inappropriate. The PQL is not really a threshold at all, but rather an acknowledgement that analytical methods have limits.

a. The PQL Is Too Low A Threshold

The threshold for reporting intentionally added CHCCs is solely dependent on analytical techniques. Ecology should recognize that modern analytical techniques are extraordinarily sensitive. Quantitation limits in the parts per million level were generally surpassed long ago.

Today, quantitation in the parts per billion level, parts per trillion level, or even parts per quadrillion level is now achievable for some chemicals. Such quantitation would require manufacturers to initiate scores of new tests, well beyond requirements for compliance with federal or state safety laws. The PQL is not only an arbitrarily variable threshold, but it is also vastly over-inclusive.

The Preliminary Cost-Benefit and Least Burdensome Alternative Analyses (the Analyses) for the proposal do not discuss the alternative of setting a threshold for reporting intentionally added components other than the PQL. Instead, the Analyses indicate generally that:

Ecology expects the information on CHCC content in children's products prompted by the proposed rule to ultimately be used to benefit consumers by assisting them in making more efficient consumption choices relative to their preferences.³

It is hard to imagine what benefit consumers will obtain by learning that a CHCC is present at the parts per billion level in a children's product. Presence is not the same as exposure (or harm, as Ecology has acknowledged), since even with handling by children either all or almost all of a CHCC will remain in the product. Where the total quantity is in the parts per billion level, the amount available for transfer is incredibly low. Consumers will not benefit at all from learning such information.

However, manufacturers and distributors of children's products would be adversely impacted. Consumers are likely to overreact to such information through avoidance of children's products containing even these extraordinarily low levels, due to lack of understanding of the relationship of exposure to risk and by reacting only to hazard. It is for reasons such as this that consumer labeling requirements limit the amount of information required to be disclosed to consumers, so as to avoid information overload and inappropriate reaction to unnecessary information.

A PQL established essentially at the limits of detection is too low a threshold and serves no constructive purpose where consumer education and choice are concerned.

b. Any Required Disclosure of Intentionally Added Components Should Have a Threshold That Takes Exposure Into Account

The PQL proposal has a different disclosure threshold for every CHCC, depending solely on the arbitrary nature of how easy or difficult it is to detect and quantify individual CHCC using available analytical methods. This variable threshold has nothing to do with the sound implementation of the underlying statute or the public interest in information on CHCC's in products. The requirement is also at odds with mainstream requirements for disclosure of hazardous components.

For the occupational sector, the benchmark protective threshold for disclosure of hazardous chemicals is OSHA's hazard communication standard. It sets thresholds of 1% for most

³ Ecology, Preliminary Cost-Benefit and Least Burdensome Alternative Analyses - Supplemental Rule Proposal (Apr. 2011), available at <http://www.ecy.wa.gov/pubs/1007035.pdf>, at 14.

hazardous chemicals, 0.1% for designated carcinogens, and only requires disclosure at lower levels if the chemical is likely to pose a health risk to employees – a determination for which exposure levels are a critical consideration.⁴

The benchmark for disclosure of hazardous chemicals in consumer products, including children's products, is the Federal Hazardous Substances Act (FHSA). It mandates consideration of actual risk from exposure to hazardous chemicals before requiring public disclosure. It defines the term "hazardous substance" as one with certain toxicological or physical hazards, but only:

if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including foreseeable ingestion by children.⁵

Thus, at the federal level, degree of exposure from use of consumer products is critical to determining whether disclosure is necessary. For acute hazards, such as toxicity, this is important due to the impact of dilution on the hazards of the mixture as a whole.⁶ For chronic hazards, risk is also critical.

This approach is well-accepted at the international level. The Globally Harmonized System of Classification and Labeling of Chemicals (GHS), developed under the auspices of the United Nations for application to industrial and commercial products as well as consumer products, specifically acknowledges the FHSA approach of risk-based disclosure for chronic hazards in consumer products.⁷

Similarly, the European Union's Toys Directive acknowledges the significance of exposure levels, providing:

Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.⁸

The proposed rule would do away with the concept of exposure by requiring all intentionally added components to be disclosed, down to the PQL. The excessive conservatism of this approach is readily apparent. Nine of the 69 CHCCs proposed by Ecology are phthalates. Section 3(c) of the CSPA prohibits six of these phthalates in children's products at levels > 1,000

⁴ 29 C.F.R. § 1910.1200(d)(5).

⁵ FHSA § 2(f)(1)(A), 15 U.S.C. § 1261(a)(f)(1)(A). The implementing Consumer Product Safety Commission (CPSC) regulations has the same definition, 16 C.F.R. § 1500.3(a)(4)(i)(A). For CPSC guidance on assessment of exposure in consumer products, see 16 C.F.R. § 1500.135(d).

⁶ For this reason, the CPSC regulations implementing the FHSA advise that for determination of acute hazards, "[t]he mixture itself should be tested." 16 C.F.R. § 1500.5.

⁷ GHS (3d rev. ed. 2009), Annex V, available at http://live.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev03/English/09e_annex5.pdf.

⁸ Directive 2009/48/EC (2009), Art. 10.2. The Toys Directive has or incorporates maximum limits for some particular chemicals, but otherwise relies generally on exposure as a factor.

ppm.⁹ Since the science and technology around the detection of chemicals is constantly evolving, the PQL for phthalates could very well be substantially below 1,000 ppm. Thus, the proposal would require the disclosure of phthalates possibly orders of magnitude below the already allowed level in children's products. In ACC's view, the PQL approach essentially eliminates the concept of a de minimis standard, as it is focused only on detection limits. More to the point, the PQL approach has no relationship to either the levels at which exposures to the substance may occur or the levels of exposure that pose an actual risk of harm.

Similarly, formaldehyde, listed on the CHCC, is widely used in textile processing as an active ingredient in fixing agents (pigment printing, coating, finishing), as cross-linking agents (non-iron, wrinkle-free finishing for cotton) and as a preservative. Formaldehyde residue in textiles is tested according to the international standard ISO 14184-1.¹⁰ International authorities, such as the Organization for Economic Co-Operation and Development (OECD), have made clear that when a textile product comes into direct contact with the skin the level of formaldehyde to be considered as acceptable is ≤ 75 ppm for children 3 years and older and adults.¹¹ This same standard is used most by textile dealers and their associations, including the American Apparel and Footwear Association. The PQL approach would fundamentally ignore relevant, well-established standards such as those published by the International Standards Organization and other consensus standards organizations.

The proposed requirement to disclose components of fragrances in children's products down to the PQL is particularly troublesome. The FDA allows fragrance components in cosmetics to be identified as "fragrance."¹² Similarly, the European Union's Cosmetics Regulation allows perfume and aromatic compositions and their raw materials to be referred to as "parfum" or "aroma."¹³ Ecology should similarly allow fragrance ingredients to be reported by such general terms.

c. Alternative Approaches to PQL Are Preferable

The CSPA, WAC § 70.240.040, does not set a threshold for disclosure of CHCCs in children's products, either for intentionally added components or for contaminants.¹⁴ Thus, Ecology may determine that a numerical threshold is appropriate, or set a threshold driven by risk.

The PQL is proposed as the threshold for intentionally added CHCCs. Ironically, the PQL concept was developed by the U.S. EPA for detecting low levels of contaminants in water and

⁹ While section 3, Rev. Code Wash. § 70.240.020, is preempted by the Consumer Product Safety Improvement Act of 2008 (CPSIA), CPSIA itself has the same 1,000 ppm ceiling for those six phthalates.

¹⁰ ISO 14184-1 http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=23871

¹¹ See 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, [OECD Trade Policy Studies Environmental Requirements & Market Access](#).

¹² 21 C.F.R. § 701.3(a).

¹³ Regulation (EC) No 1223/2009, Art. 19.1(g).

¹⁴ CSPA § 5, Rev. Code Wash. § 70.240.040, simply requires notification that a children's product "contains" a CHCC, without further elaboration on what that term means in this context.

has not been applied in practice to consumer products.¹⁵ If components are intentionally added, then the manufacturer knows of their presence, and knowledge of the detection limit (the PQL) is not necessary to trigger disclosure.

Additionally, FDA's requirements for disclosure of intentionally added components in cosmetics do not set a threshold. If a manufacturer intentionally adds a component (whether or not hazardous), the manufacturer knows it must disclose that component, subject to trade secret protections.¹⁶ That is the same approach taken in the European Union's Cosmetics Regulation, which simply requires a list of intentionally added ingredients.¹⁷

Ecology should learn from California's experience with trying to regulate methods of detecting very low levels of chemicals listed under Proposition 65. CalEPA's Office of Health Hazard Assessment (OEHHA) adopted a regulation on methods of detection¹⁸ that proved difficult to apply in practice, and, the office ended up repealing the regulation in 2005.¹⁹ A 2004 rulemaking notice explained:

In recent years, litigants and courts have had difficulty interpreting and applying Cal. Code of Regs., Section 12901, particularly in the context of consumer products exposures. Recent cases such as *Mateel Environmental Justice Foundation v. Edmund Gray et al.* (2004) and various trial court decisions have highlighted issues with the application of the regulation to particular types of exposures as well as the difficulties some litigants encounter in identifying the proper method of analysis for a given chemical in a particular medium. Therefore, OEHHA has determined that amendments to the regulation are necessary to provide a level of certainty for persons subject to the provisions of the Act.²⁰

While at the time OEHHA indicated that it would adopt a replacement provision, in the years since then it has been unable to do so.

The problems that California experienced with its counterpart to Ecology's proposed PQL provision are likely to be experienced by Washington if that provision is adopted. Ecology should not adopt it. Instead, it should either set a numerical threshold, such as 0.1% (1000 ppm) – an internationally recognized *de minimis* level that is consistent with existing regulations and economically and technically feasible. Alternatively, for chemicals where an authoritative body has established another acceptable threshold in products with exposure to children, this would be the limit above which intentionally added CHCC chemicals would need to be identified. If such a limit has not been established, then the proposed threshold of 0.1% would be the *de minimis*.

¹⁵ See EPA, National Primary Drinking Water Regulations; Synthetic Organic Chemicals; Monitoring for Unregulated Contaminants, 52 Fed. Reg. 25690, 25699-700 (July 8, 1987).

¹⁶ See 21 C.F.R. § 701.3.

¹⁷ Regulation (EC) No 1223/2009, Art. 19.1(g).

¹⁸ Former Cal. Code. Regs. tit. 22, § 12091.

¹⁹ OEHHA, Notice of Repeal of Regulations Title 22, California Code of Regulations Section 12901 Methods of Detection [03/12/05], available at <http://www.oehha.org/prop65/law/12901repeal.html>.

²⁰ Notice of Proposed Rulemaking, Title 22, California Code of Regulations Amendment to Section 12901 Methods of Detection Safe Drinking Water and Toxic Enforcement Act 1986 [06/04/04], available at <http://www.oehha.org/prop65/law/cnrmethoddetect.html> (citation omitted).

2. Notification of Contaminants Should Not Be Required

The proposal would require notification of contaminants in children's products present at levels > 100 ppm. This requirement should be dropped. Ecology should follow the example of many other notification programs and limit notification to intentionally added ingredients. For example, the following programs relate only to intentionally added ingredients, not contaminants:

- FDA's cosmetics labeling requirements²¹
- The EU's Cosmetics Regulation²²
- California Safe Cosmetics Act of 2005²³
- Washington's toxics in packaging law²⁴, as well as similar laws in California,²⁵ Connecticut,²⁶ and Minnesota²⁷
- Restrictions on the sale of batteries with intentionally added mercury in Arkansas,²⁸ Florida,²⁹ and Michigan³⁰

Maine's Regulation of Chemical Use in Children's Products, the source statute for the CSPA, has been interpreted by the Maine Board of Environmental Protection to apply only to intentionally added components in children's products. The Board adopted a definition of "intentionally added" in its implementing regulations³¹ and limited the scope of its regulations on bisphenol A³² and nonylphenol and nonylphenol ethoxylates³³ to children's products to which those chemicals have been intentionally added.

Ecology itself has recognized that most of the benefit from notification will come from the notification of intentionally added components:

²¹ 21 C.F.R. § 701.3(l) (excluding incidental ingredients).

²² Regulation (EC) No 1223/2009, Art. 19.1(g) (excluding impurities and subsidiary technical materials).

²³ Cal. Health & Safety Code § 111791.5(d) (excluding incidental ingredients also excluded by FDA in 21 C.F.R. § 701.3(l)).

²⁴ Rev. Code Wash. § 70.95G.020 (section applies only to listed metals that have been intentionally introduced in packaging).

²⁵ Cal. Health & Safety Code § 25213 (prohibiting packaging to which regulated metals have been intentionally added).

²⁶ Conn. Gen. Stat. § 22a-255i (prohibiting packaging to which listed metals have been intentionally added, as opposed to being incidentally present).

²⁷ Minn. Stat. § 115A.965 (same).

²⁸ Ark. Code. Ann. § 8-10-301 (prohibiting sale of batteries with intentionally added mercury, as opposed to incidentally present mercury).

²⁹ Fla. Stat. Ann. § 403.7192 (prohibiting sale of batteries containing intentionally added mercury).

³⁰ Mich. Comp. Laws § 324.17105a (same).

³¹ Code of Maine Rules § 06 096 880.1.N.

³² Code of Maine Rules § 06 096 882.1.A.

³³ Code of Maine Rules § 06 096 883.1.

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.³⁴

Ecology should follow the many examples followed above and limit its notification requirements to intentionally added components.

3. 100 ppm Is Too Low a Threshold for Contaminants

Assuming that Ecology nevertheless decides to require notification for contaminants, it would be helpful to have an objective threshold to help manufacturers know the limits of what must be notified. However, 100 ppm, while an improvement over the previously proposed 40 ppm, is still too low.

In rejecting commenters' suggestions that 1000 ppm (0.1%) might be an appropriate threshold for contaminants if contaminants are to be notified, Ecology said, "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."³⁵

However, 100 ppm is just as arbitrary as 1000 ppm; and is simply not relevant in the absence of substance-specific risk assessments.

Ironically, Ecology cited EPA's Design for the Environment Program (DfE) as support for the 100 ppm reporting threshold for contaminants.³⁶ EPA has recently revised its DfE Standard for Safer Cleaning Products to require disclosure of intentionally added ingredients, but no disclosure of contaminants is required. Moreover, reference to the DfE Program is inappropriate in a regulatory context, as DfE is a voluntary program.

For any contaminant threshold selected by Ecology, ACC supports the exemption for situations where a manufacturer has in place a manufacturing control program and exercises due diligence to minimize the presence of a particular contaminant. However, this exemption should apply where the contaminant is present above the threshold despite such program and due diligence. For example, formaldehyde, one of the proposed CHCCs, sometimes forms spontaneously in products without having been intentionally or unintentionally added. Manufacturers should not be liable for non-reporting of formaldehyde above the threshold if it forms spontaneously above the threshold despite manufacturing control programs and due diligence.

Aggregate Gross Sales and Non-Children's Products

The criteria for establishing manufacturer categories to determine a reporting schedule is inappropriate. As outlined in WAC § 173-334-110(3), the proposed "annual aggregate gross

³⁴ Ecology, "Children's Safe Product Act – Reporting Rule Summary and Response to Public Comment on Original Rule Proposal" (May 4, 2011), available at http://www.ecy.wa.gov/programs/swfa/rules/pdf/cspa_response1.pdf, at 15.

³⁵ Id. at 13.

³⁶ Id. at 15.

sales” criterion is not a relevant indicator for the phase-in of reporting requirements, as it is not related to actual product exposure. From a safety standpoint, the approach incorrectly assumes that gross sales volume is an accurate proxy for children’s exposure.³⁷ This assumption will have the effect of vastly overstating the number of products in question. In addition, Ecology’s rationale for the disclosure of sales outside the State of Washington is unclear – undoubtedly those sales are not subject to the regulation, and it is not clear how and when the department may use the information. Regardless of manufacturers’ market share in the State or across the national economy, those individual products that result in exposures of greatest concern in the State of Washington should be Ecology’s focus.

Additionally, Ecology should clarify when a company manufactures both children’s products and non-children’s products. Does the manufacturer only need to consider the children’s product sales to determine what manufacturer category it is in? Does Ecology intend that “annual aggregate gross sales” includes all products manufactured by a company, and not just children’s products? Does Ecology intend just the children’s products that contain CHCC substances? If Ecology intends to require manufacturers to report presence of the most dangerous substances first, accounting for hazard and exposure, the CHCC list must be prioritized. ACC requests that Ecology remove or revise the aggregate gross sales criterion. If Ecology does not strike the sales volume provision, it must make clear that the values used to group by size relate only to children’s products containing the CHCC that would trigger reporting.

ACC also urges Ecology to remove Product Tier 4 from the proposed regulations. Ecology indicates that reporting for Tier 4 (Children’s product components that during reasonable foreseeable use and abuse of the product would not come into direct contact with the child’s skin or mouth, e.g. inaccessible internal components) will be determined on a case-by-case evaluation and may be required by amendment of the regulations. It is difficult to understand the necessity of Tier 4, particularly since there is no contact that should warrant concern.

ACC appreciates Ecology’s recognition of innovation and the continuous search for improved products, noted in WAC § 173-334-110(5). The proposal enables manufacturers who present documentation that they are conducting safer alternative assessments for CHCCs, with the intent of moving away from or reducing the use of CHCCs, to extend the reporting requirement by 12 months. It remains unclear as to what type of documentation is necessary to support a manufacturer’s alternative assessments research. For the most efficient use of this allowance, Ecology should explicitly communicate the type of documentation that will meet the requirements of the reporting extension.

Protection of Confidential Business Information

ACC strongly agrees with the need to protect Confidential Business Information and commends Ecology for explicitly stating in WAC § 173-334-080(4), “[i]f a reporting party believes the information being provided is confidential business information (CBI), in whole or in part, it may request that the department treat the information as confidential business information...”

³⁷ Id. at 6.

ACC encourages Ecology to continue to advocate for the protection of American innovation and jobs through the protection of CBI.

Revisions of the CHCC List

ACC commends Ecology for including a mechanism to revise the CHCC list on an ongoing basis. As proposed, WAC § 173-334-060 allows for chemicals to be added or removed from the CHCC list by amending the regulation.

Quality of Scientific Information

Although not defined in WAC § 173-334-040, ACC supports the approach of the proposed regulations, requiring decision making to be based on “credible peer-reviewed scientific information.”³⁸ We also recommend that the proposed regulation be harmonized with international criteria for establishing the appropriate quality, reliability, and relevancy of experimental data to human health risk assessments. Additional background on the importance of this to making sound scientific decisions from which to regulate is provided below.

Studies performed under Good Laboratory Practice (GLP) standards and according to validated testing guidelines are the data submissions that regulatory agencies typically use as the primary source of experimental information from which decision making activities are made on a particular chemical,^{39,40,41} although basic exploratory research data (*i.e.*, peer-reviewed scientific articles) from academic or government research laboratories are sometimes available to inform regulatory decision making.⁴² There are, however, several caveats with using exploratory research data because they are almost never conducted under GLP or in accordance with a validated testing guideline, rather these data are typically reported as published summaries in the peer-reviewed literature, with the underlying raw data being very difficult or sometimes impossible to obtain from the investigators.^{43,44,45,46,47} Therefore, assessing the quality, reliability,

³⁸ WAC § 173-334-070(4)(c).

³⁹ 40 CFR Part 792, § 792.1(a) and (c).

⁴⁰ METI (2005) *Chemical Control Legislation in Japan Outline of the 2003 Partial Amendment to the Chemical Substances Control Law*, pp. 1-29, at p. 10, available at <http://www.safe.nite.go.jp/english/kasinn/pdf/chemconpresen.pdf>.

⁴¹ EC (2006) *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)*, OFFICIAL JOURNAL OF THE EUROPEAN UNION L 396, at p. 26.

⁴² ECHA (2008a) *Guidance on information requirements and chemical safety assessment, Chapter R.7a: Endpoint specific guidance*, GUIDANCE FOR THE IMPLEMENTATION OF REACH, pp. 1-428, at p. 15, European Chemicals Agency, Helsinki, Finland.

⁴³ EPA (2008a) *Toxicological review of decabromodiphenyl ether (BDE-209) (CAS No. 1163-19-5), In support of summary information on the Integrated Risk Information System (IRIS)*, EPA/635/R-07/008F, pp. 1-126, at p. 32 (footnote 1) (“Attempts to obtain numerical values and other information on the data from the authors were not successful.”), US Environmental Protection Agency, Washington, DC, available at <http://www.epa.gov/ncea/iris/toxreviews/0035-tr.pdf>.

and relevancy of basic exploratory studies is a complicated, but essential requirement for ensuring that regulatory risk assessments are based on credible scientific information.

Klimisch *et al.* (1997) proposed the following systematic approach for evaluating the quality and reliability of studies (*e.g.*, GLP/guideline studies and exploratory research studies) for use in risk assessment:⁴⁸

1. *Reliable without Restrictions.* This includes studies or data from the literature or reports which were carried out or generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline (preferably according to GLP) or in which all parameters described are closely related/comparable to a guideline method.
2. *Reliable with Restrictions.* This includes studies or data from the literature, reports (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.
3. *Not Reliable.* This includes studies or data from the literature/reports in which there are interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (*e.g.*, non-physiologic pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for an assessment and which is not convincing for an expert judgment.
4. *Not Assignable.* This includes studies or data from the literature, which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).⁴⁹

⁴⁴ EPA (2008b) *Toxicological review of 2,2',4,4',5,5'-hexabromodiphenyl ether (BDE-153) (CAS No. 68631-49-2), In support of summary information on the Integrated Risk Information System (IRIS)*, EPA/635/R-07/007F, pp. 1-66, at p. 22 (footnote 1) (“Attempts to obtain numerical values and other information on the data from the neurobehavioral studies were not successful.”), US Environmental Protection Agency, Washington, DC, available at <http://www.epa.gov/ncea/iris/toxreviews/1009-tr.pdf>.

⁴⁵ EPA (2008c) *Toxicological review of 2,2',4,4',5-pentabromodiphenyl ether (BDE-99) (CAS No. 60348-60-9), In support of summary information on the Integrated Risk Information System (IRIS)*, EPA/635/R-07/006F, pp. 1-128, at pp. 30-31 (footnote 1) (“Attempts to obtain numerical values and other information on the data from the neurobehavioral studies were not successful.”), US Environmental Protection Agency, Washington, DC, available at <http://www.epa.gov/ncea/iris/toxreviews/1008-tr.pdf>.

⁴⁶ EPA (2008d) *Toxicological review of 2,2',4,4'-tetrabromodiphenyl ether (BDE-47) (CAS No. 5436-43-1), In support of summary information on the Integrated Risk Information System (IRIS)*, EPA/635/R-07/005F, pp. 1-85, at p. 29 (footnote 1) (“Attempts to obtain numerical values and other information on the data were not successful.”), US Environmental Protection Agency, Washington, DC, available at <http://www.epa.gov/ncea/iris/toxreviews/1010-tr.pdf>.

⁴⁷ In contrast to notes 45-47, see: EPA (2009) *An approach to using toxicogenomic data in U.S. EPA human health risk assessments: A dibutyl phthalate case study*, EPA/600/R-09/028A, pp. 1-266, at p. xvi (“We gratefully acknowledge [study author] for providing raw data from the Liu *et al.* (2005) study.”), US Environmental Protection Agency, Washington, DC, available at http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=490614.

⁴⁸ Klimisch, H.-J., Andreae, M., Tillmann, U. (1997) *A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data*, REGULATORY TOXICOLOGY AND PHARMACOLOGY, Vol. 25, pp. 1-5.

⁴⁹ *Id.* at pp. 2-3.

The ‘Klimisch codes’, as they have since become known, are similar to the tiered approach used by EPA for evaluating data under the High Production Volume (HPV) Challenge Program,⁵⁰ and are proposed by the OECD, along with the EPA’s tiered approach, for use in the OECD HPV program.⁵¹ The Klimisch codes have also been formally adopted by the European Chemicals Agency (ECHA) for use in product registrations under the European Commission’s chemical control law known as “REACH.”⁵² As noted by the ECHA, “[t]he knowledge of how a study was carried out and consequently its relevance and reliability, is a prerequisite for the subsequent evaluation of this information.”⁵³ It is for these reasons that ACC recommends that Ecology’s draft regulation set forth an objective and transparent set of criteria (*e.g.*, Klimisch codes) for ensuring data quality, reliability, and relevancy for any decision-making activities made under the final regulation.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Emily Kolarik (emily_kolarik@americanchemistry.com; 202-249-6127). 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

⁵⁰ EPA (1999) *Determining the adequacy of existing data [Draft]*, pp. 1-26, at pp. 2-3, US Environmental Protection Agency, Washington, DC.

⁵¹ OECD (2005) *Chapter 3: Data evaluation*, Manual for Investigation of HPV Chemicals, pp. 1-13, at p. 3, Organisation for Economic Co-operation and Development, *available at* <http://www.oecd.org/dataoecd/13/15/36045203.pdf>.

⁵² ECHA (2008b) *Guidance on information requirements and chemical safety assessment, Chapter R.4: Evaluation of available information*, GUIDANCE FOR THE IMPLEMENTATION OF REACH, 1-23, at p. 7, European Chemicals Agency, Helsinki, Finland.

⁵³ *Id.* at p. 9.

Grice, Joshua (ECY)

From: Tim Zacharewski [tzachare@msu.edu]
Sent: Wednesday, June 15, 2011 6:51 AM
To: Williams, John (ECY)
Subject: Children's Safe Product Act - comment

Mr. John R. Williams
Washington State Department of Ecology
PO Box 4760
Olympia, WA 98504-7600

Dear Mr. Williams:

I am writing to express my concern with the inclusion of all phthalates as chemicals of concern for children as part of the proposed rule to the Children's Safe Product Act - Reporting Rule.

This regulation is of particular interest to me given my research interests in the toxicology of phthalates.

Phthalates are plasticizers found in every day consumer products.

They are used in consumer products to soften plastic and extending they applications. The move to target all phthalates is problematic given the ssafety and testing record of some phthalates, notably the high molecular weight phthalates such as DNIP and DIDP. High molecular weight phthalates have undergone extensive scientific scrutiny and passed numerous government safety assessments and reviews. I have personally participated in a comprehensive review of the toxicity of phthalates for the National Toxicology Program and can affirm their safety. For example, DINP and DIDP were found to have "minimal" and "negligible" concern for reproductive and developmental toxicity. In addition, data collected by the Centers for Disease Control and Prevention found that even when humans are exposed to phthalates, the levels fall well below safety limits established by both the European Union and the Environmental Protection Agency itself.

The state of Washington should be cautioned that listing all phthalates as "chemicals of concern". Not only is there a lack of scientific evidence for such a listing but this could also have significant unintended consequences. Listing all phthalates as chemicals of concern to children would require manufacturers to seek alternatives. Yet none of the alternative plasticizers have been as extensively reviewed by any government agency. Consequently, replacing proven-safe chemicals with alternatives that have not been as thoroughly tested and reviewed does not resolve the problem and may expose consumers (especially children) to potentially dangerous chemicals.

Regulations need to be based on the best scientific data available. I strongly urge the Department of Ecology to reconsider listing all phthalates in the Children's Safe Products Act.

Sincerely,

Tim Zacharewski

Tim Zacharewski, Ph.D.
Professor of Biochemistry & Molecular Biology Michigan State University Department of Biochemistry & Molecular Biology Center for Integrative Toxicology East Lansing, MI 48824-1319

TZ office tel: 517-355-1607

TZ lab tel: 517-353-1944

e-mail: tzachare@msu.edu

<http://www.bch.msu.edu/~zacharet>

NFSTC fax: 517-432-2310

BMB fax: 517-353-9334

NFSTC tel: 517-432-3100

BMB tel: 517-355-1600

Grice, Joshua (ECY)

From: Elizabeth Zimmerly [ezimmerly@gmail.com]
Sent: Monday, June 13, 2011 9:42 PM
To: Williams, John (ECY)
Subject: Comments on the Children's Safe Product Act Reporting Rule

Dept. of Ecology

Dear John R. Williams,

As a parent of a 3- year old boy, I am deeply concerned about toxic chemicals being in toys and other children's products. I have done a lot of research to try to find non-toxic toys and products, but there is not enough specific information on many product labels. It is appalling to see your sweet child putting toys in their mouths that may be harmful (a normal behavior not just for babies but even through age 2, 3 and sometimes older). Children are exposed to toxic chemicals directly through this hand-to-mouth behavior and also through constant contact with toys day and night. Children's small, growing bodies are affected more severely by toxic chemicals than adults. Our children deserve stringent protections. Clear information on product labels and in databases plus strong enforcement of chemical reporting is critical to help parents protect their children.

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 disclose the specific products a chemical is used in, not just a broad product category like "dolls".
- * Eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant.
- * Require all makers of children's products intended for children 3 and under to report immediately.
- * Ensure the public has wide and easy access to the information on the chemicals.

Thank you for your consideration,

Elizabeth Zimmerly
10033 63rd Ave. S.
-
Seattle, WA 98178

CSP Rule

Public Meeting

June 8, 2011

Transcription: Record of Oral Testimony

I'm Angela Fritz, Hearings Officer for this hearing. This evening we are conducting a hearing on the proposed Children's Safe Product Reporting Rule. Let the record show that it is 7:27 on June 8th 2011 and this hearing is being held at Ecology's Headquarters in SWRO 300 Desmond Way SE in Lacey. Legal notices of this hearing were published in the Washington State Register on May 4, 2011, Washington State Register No. 11-10-088. In addition, notices of the hearing were sent by list serve to approximately 340 interested people including everyone who provided comment during the last comment period and provided an email address. I will call people up to provide oral testimony based on the order I have received your sign in cards. Once everyone who indicated they would like to testify has had the opportunity, I will open it for others. We have 7 people signed in to provide formal testimony. Remember, comments should be about 5 minutes. I will give you a reminder when you have 1 minute remaining. When you reach 1 minute remaining, I will ask you to summarize your comments so the next person can come up and testify. When I call your name, please step up to the mike, sit down; state your name and your address for the record. Speak clearly so we can get a good recording of your testimony.

We will begin with Mary Ann Thomas followed by Pat Dickason.

Hi, my name is Mary Margaret Thomas. My address is 2429-A NW 58th Street Seattle, Washington 98107. I'm here today because I am a nurse working on my Masters in Community and Public Health and I wanted to thank you for moving forward with this rule. I grew up in Louisiana in a region of the country that's known as "Cancer Alley" and I'm really thankful to the State of Washington for passing legislation and creating a precedence in this country for

pieces of legislation such as the CSPA. CSPA was passed in response to a very real problem. Harmful chemicals in the products that children play, eat, and sleep with everyday. A study by Kate Davies found that in 2004, Washington State spent an estimated \$1.875 billion dollars on pediatric diseases and disabilities related to toxic chemical exposures. These preventative measures and legislation can help reduce the related medical costs and protect our children's health. One of the biggest barriers in regulating consumer products is the lack of information about harmful chemicals in everyday items. Several providers I know and friends with young children are constantly asking me how to tell if a product is safe for children and parents suffer an immense amount of guilt in the fact that they can be inadvertently exposing their children to harmful chemicals. The hard answer I have to give them is that at this point we cannot be 100% certain of the safety of most of children's products on the market today. The CSPA list and reporting requirements are valuable first steps in a country where government agencies charged with keeping us safe are unable to do so because they don't have the necessary information to identify and take action on products that pose a threat to children's health. Every month, more harmful chemicals are being found in children's products. Toxic flame retardants that were recently removed from pajamas are now being found in changing pads and crib mattresses. Only when manufacturers are held responsible for disclosing product chemicals and required to use safer alternatives can we begin to address the issue. The synthetic preservative paraben for example was found in over 25,000 personal care products that were evaluated by the environmental working group. Parabens are known to be endocrine disrupting chemicals. They can impact estrogen and testosterone levels as well as sperm counts in males. Parabens were also found in 19 out of 20 women in their breast cancer tumors and they may be partially to blame for the fact that women or young girls rather in the United States are reaching puberty an average of 2 years earlier than they did 40 years ago. This earlier menses from my studies in public health, we know that this can lead to a cascade of other physiological as well as psychological issues for these young girls across their life span. I also wanted to thank you for some of the changes incorporated in this version of the rule and the addition of phthalates and cadmium to the list of chemicals to be reported. To protect children's health and the environment, the rules should also be improved in 3 different ways.

First of all, we need to require companies to disclose how widely the chemicals used and the product category. The law currently allows the agency to collect data on chemical use for each ...but the agency isn't proposing to collect at this level of detail. At the very minimum...the agency needs to know how many product units contain a particular chemical to get a sense of the magnitude of the problem. Secondly, we need to eliminate loopholes that let companies off the hook for reporting if the chemical is in the product listed as a contaminant. And thirdly, we need to require all makers of children's products intended for children 3 and under to report immediately. Don't just limit reporting only products that are mouthable because kids at 3 years old put everything in their mouths. In conclusion, Ecology should be planning to include a plan on how they will ensure the public has a wide and easy access to the information on the chemicals. Thank you for your hard work on this rule and please continue to put children's health first and ensure that companies are exposing toxic chemicals.

Pat Dickason followed by Chris Guay.

Good evening, I'm Patricia Dickason and I'm Vice President for the League of Women Voters in Washington State and my address is 4617 Springfield Lane SE Lacey, Washington 98503. I'm here to testify that the League of Women Voters Washington strongly supports the provisions of the Children's Safe Product Act and the reporting rule. We base our support on League of Women Voters United States position [Early Intervention For Children At Risk](#) and League of Women Voters Washington Natural Resources positions that support prevention of harm before damage occurs. I'm going to echo my predecessor's comments somewhat. And I want to say thank you for the work that you've done in developing the rule that would provide information about chemicals present in toys and consumer products. This information will help consumers know what is contained in the products they purchase for their children and government agencies would benefit from knowing about product content so they can take action against products that pose threats to children's health. Thank you for some of the changes incorporated in this version of the rule. For example, it makes sense that manufacturers that intentionally add toxic chemicals to their products be required to report no

matter what level they occur in the product. We also appreciate the addition of phthalates and cadmium to the list of chemicals that must be reported. League of Women Voters of Washington concurs with others regarding needed improvements to the rule that will protect children's health and the environment. Number 1: require companies to disclose how widely the chemical is used in the product category. The law allows the agency to collect data on the chemical used for each product unit but the agency isn't proposing to collect this level of detail. At the very minimum, the agency needs to know how many product units contain a particular chemical to get a sense of the magnitude of the problem. Number 2: eliminate loopholes that let companies off the hook for reporting if the chemical is in the product as a contaminant. Number 3: Require all makers of children's products intended for children ages 3 and under to report immediately. Don't just limit immediate reporting to only products that are mouthable because children that age and under put everything in their mouths as you well know if you are parents, grandparents, aunts, uncles or whatever, that's extraneous. But we also believe that ecology should include a plan on how they would ensure the public has wide and easy access to the information on the chemicals that are in products. Thanks for your hard work and please put children's health first and ensure that companies come clean on toxic chemicals. Thank you.

Chris Guay followed by Laurie Valeriano.

My name is Chris Guay, I'm from Cincinnati, Ohio and actually I have just one comment and that is; in trying to put this rule together, I think you've done a lot of very, very good things in terms of what you've put together with this rule. The one thing that I would suggest though you need to look at very carefully is, "how do you make sure that every company subject to the rule will interpret the rule the same way and provide you the same information?" My concern right now is that the way the rule is structured it's still too much open to interpretation so company "A" trying to do the right thing may do one thing, company "B" may take a different approach, company "C" may take a different approach, it will be hard to compare what you get because some companies will look at one set of data and say, "We're not required to report" and the

other one will look at that same data and say, "We are required to report". So I think it's important to look at it from a standpoint of if you were implementing the rule do you have enough clarity in the instructions and what's there so that you're going to get the same information from all companies. My concern is that there's not enough especially when it comes to the definition and the scope of what is a children's product and what is in scope. I still think there's too much fuzziness with that and therefore you're going to get different companies will take a different approach in some terms of what is and is not a children's product and therefore you're going to potentially miss some that you think you're capturing and you may get data from companies that you're not expecting because they've looked at it very, very, you know interpreted it in a very narrow way or a very expansive way from a standpoint of figuring "if in doubt; report". Where you make it information from like one product category from one company and nobody else where other ones may not sell. The one suggestion I have especially when it comes to the children's product definition and what the scope of that is the more you can put into either the regulation or the guidance to provide that clarity. I think the better the data you get the more consistent the data you'll get as you do that. That is my one and only comment. Thank you.

Laurie Valeriano followed by Alex Hamling.

My name is Laurie Valeriano, I'm the Policy Director for the Washington Toxics Coalition and my address at the Washington Toxics Coalition is 4649 Sunnyside Avenue N. Seattle 98103. Thank you very much, I appreciate this opportunity to provide comment on this important rule and we really appreciate the Department of Ecology's work on this rule. It's really important to protect children's health as well as the environment. This act that was adopted in 2008 was a critical groundbreaking law that really can help to fill major gaps we have about harmful chemicals that are lurking in everything from toys and tween lotions and perfumes to car seats and bedding. We already know that the problem is a lot bigger than the original thing that sparked a lot of this which was lead in toy trains and we know that federal law, the Toxics Substances Control Act, really doesn't at all provide the level of safety and health data that is needed to properly

regulate chemicals. So whether it's baby bottles made with bisphenol A, phthalates in vinyl toys, cadmium in Shrek glasses or toxic flame retardants in baby products we know really that no one is minding the store when it comes to chemical regulation and it's virtually impossible for consumers right now to figure out what chemicals are used in products and as a person working on these issues for 2 decades, not even I can figure this out sometimes. My daughter came home with this lovely item that you place in your mouth and you roller skate at a roller rink with it so your mouth lights up. Well immediately, I took this away from her on Saturday and thought, "What is this?" and I fortunately have a \$30,000 XRF gun at the office that I could bring and test this product, well, I couldn't figure out what the plastic was because the gun doesn't test the plastic but I could identify the inside components which I believe are lead solder at around 1000 to 2000 parts per million lead. Now it's not right that I have to even worry about this product being put in my child's mouth if it's out in the shelves, if it's you know something she can buy and have access to, it should be safe bottom line. So, it's really, I mean, clearly with the absence of federal regulation, clearly with the absence of information, it's really up to the states right now to protect children and families. In Washington State, we're lucky to have this law so we really need to implement it as best we can and get the best information for consumers as well as the government in order to protect children from harmful chemicals and I really appreciate, we really appreciate some of the changes that you made from the last version including eliminating 40 parts per million trigger level and moving to intentionally added approach with the pql. We appreciate that you clarify the intent of the agency to put the information on the website so that consumers could have information, access to the information and we appreciate the addition of the phthalates to the list of the chemicals of high concern for the children. But really we have a couple of main concerns and our biggest concern is that we're not going to be getting specific product information and basically the requirements of the law is simple. It's that every year, manufacturers of children's products submit a report if their product contains a chemical of high concern for children that is on the list. That's it, it's very simple, it's a requirement of the law. That's what the rule should do. One because the government needs the information to assess the extent to which these chemicals

are used in products and to figure out exposure and second add some strong protections and restrictions on harmful chemicals that range from carcinogens to reproductive toxicants. Consumers need this information to make the right choices for their families. So we think it's pretty simple and the rule should require that product specific information be reported by manufacturers and right now, its product categories. And I'll give you a couple of examples of why this doesn't work. Fragrance is a big issue, no I need more time. Fragrance is a big issue that this law could really highlight for the consumers and right now, companies can just say fragrance. We know this contains diethyl phthalate which is on the list of chemicals of high concern for children but under the rule, Elizabeth Arden would just have to report or their trade association report to ecology that they use fragrance and you know, actually they use fragrance, DEP in fragrance, cause fragrance is the "brick category" for beauty products. Right? That doesn't help me as a consumer, it also really doesn't help the agency to figure out exposure because we don't know even the extent to which it's used, how many products, how popular this is, so we really need better information and more specific product information. Same thing with things like this lip gloss which has again, it just say's fragrance, they can hide the information that this might be a phthalate which is often used for fragrance. It just doesn't work. There's warnings on this product that says, "Keep out of reach of children under eight" "Do Not Eat". Its lip gloss, I mean how do you not eat lip gloss? And if it had DEP or other phthalates, we need to know as consumers. So right now the law doesn't work. Well to summarize, I just want to say that there are great changes that you've made to the rule but still there's this glaring error. There's also 2 major loopholes that we think exist in the rule and we'll submit those in writing but I did want to request that one other chemical and possibly another one be added to the chemical list and that is a flame retardant which is TDCPP or chlorinated Tris, because we know that that chemical is being used as a substitute chemical for banned penta which is a pbde that Washington State banned a number of years ago and so we think that it's critical, it's a probable carcinogen known by CPSC and we now know it's in a number of children's products that have been tested as well as house dust and other things and I will end there but I had other really compelling testimony.

And please submit those as written comments. Next we will have Alex Hamling followed by Dave Galvin.

Hello, my name is Alex Hamling, I live at 6410 9th Ave NE Apt. 304 Seattle Washington 98115. My name is Alex Hamling, I'm a pediatrician in the Seattle area and work through Seattle Children's Hospital. I became a doctor specifically in pediatrics because I'm interested in the care of children's health. As I take them on as my patients I acknowledge that we all share a responsibility in their health in creating a world that is continuing to be safe for them, sustainable, and allows for viability. Why I'm here today is because I'm a pediatrician, I'm especially concerned in that our children's health and exposure to environmental toxins. Children are much more vulnerable to chemical exposures when compared to adults. Children's bodies are very different than adults. Per body weight, they eight more, they breathe more, they drink more and thus they receive a greater exposure. They also carry a longer time period of holding on to these environmental chemicals. Children ornate hand to mouth play and behaviors that increase their direct exposure to toxins in our environment are also detrimental. Depending on the timing of these interactions they could lead to psychological and developmental delays. Ultimately the great proportions of toxins that enter the children's bodies stay there longer, allowing them more time to exert their damaging effects. These chemicals continue to put children at risk for cancer, developmental diseases and other health issues. It's my belief that all children have the right to reach their full potential and it's my goal in caring for these children to ensure that they have the potential and the opportunity to reach what they want but there are enumerable variables throughout the course of their life that are beyond my control and starting the list is a precedence of toxic chemicals in our products, in our homes, and in our environment that ultimately do end up in our bodies. We all have a responsibility to ensure that children's continued development in an environment in which they can reach and maintain their full potential and are protected from exposures to harmful chemicals that adversely affect their health. Making the products that we bring home each and every day is essential for securing their healthy future. It's important that products are known to be safe and free of toxic chemicals prior to them being available to

children. We need to act now and prevent detrimental health effects related to harmful chemicals before they occur. We have known enough to act on many chemicals already and have done so and should continue to do more. Passing this legislation in 2008 as well as many bills before this shows that Washington State does have a major priority and a stake in this. The list of reporting requirements are a good first step and Washington State should be proud of its leadership in initiating this legislation but the task is far from complete. Actions we take today to address dangerous chemicals, promise to help infants, children, schools, and communities. To delay actions means that products containing harmful chemicals will continue to be bought in our homes, brought to our schools, and available in our communities. These will result in the continued exposure and detrimental effects. The Washington State Medical Association, the Washington State Chapter for the American Academy of Pediatrics, the Washington State Nurses Association and the Washington State Public Health Association have all expressed strong support in the implementation of this bill. I want to thank you very much for your attention on this matter and our continued efforts to protect our children in the environment in which they live.

We'll have Dave Galvin followed by Jessie Dye.

Thank you, my name is Dave Galvin. I work for King County. My address is 130 Nickerson Street in Seattle 98109. The program that I work on is referred to as the local hazardous waste management program and the program provides education and technical assistance on reducing exposures to potentially hazardous chemicals to a number of businesses in the area including child care providers to schools and teachers to community groups as well as to the general public especially to parents of young children. In addition to providing information and advice to our local rate payers, we also collect for safe disposal left over products that contain lead, mercury, cadmium, ruminated flame retardants and a number of other hazardous chemicals at significantly public expense so we have an interest in the implementation of this law and we commend ecology for its thorough process to date. So my only comment tonight other than encouraging us to get on with it and fully implement the law is a specific issue that

we also commented on earlier in the public record that we think there's a significant gap in the list by not including lead. So of all the chemicals that should be on the list, we probably know the most about lead and it's the one with the longest history and yet we still see it in a number of products. It's one of the significant issues we are continually asked about in our local program and it just seems like a glaring gap to not include lead in this CHCC list for Washington State. Now ecology's explanation is that lead is not included in order to avoid some potential legal challenges because of the federal preemption. I guess our reaction to that is that one: it's important enough to include lead that we should just do it regardless of potential concern about legal challenges from federal preemption and secondly, our reading of the law shows that reporting of chemicals in products is not preempted by the federal law so it doesn't seem to us to be a rational reason for not including one of the most significant hazardous chemicals that our children are exposed to. So we encourage you to include lead in the final list otherwise get on with implementation. Thank you very much.

Jessie Dye followed by Bill Alkire.

Thank you. My name is Jessie Dye, my address is 1806 North 48th Street Seattle, Washington 98103. I'm here on behalf of Earth Ministry which has about 3000 members of the faith community from many denominations and faith traditions statewide and about 500 churches and denominations. There is no issue more important to the faith community than protecting children's safe products, than protecting children in a wide variety of ways. It is also very important to the public. Our information indicates that the public in general supports protection of children and controlling toxic chemicals in their products by about a 75% margin but in particular the faith community. We were very involved in passing the bill originally a few years ago including the Washington State Catholic Conference, the Lutheran Public Policy Office Earth Ministry and Interfaith Power and Light, the list goes on and on of all the faith communities that came out in support of this bill originally. Today, I have four specific asks for you in terms of the regulation concerning the bill. First of all, we ask the companies disclose how widely the chemical is used in the product category. The regulation is very important so

that ecology knows the chemical data on each product unit. Secondly, we're not happy with the loopholes that let companies off the hook for reporting chemicals if it's an accidental contaminant. If it's in there it needs to be disclosed. Thirdly, we want all makers of children's products to report immediately. There's no reason to put this off any further. It needs to be included now. And fourthly, we want to make sure that the public has access to information regarding what is in children's products right away. As we've heard and I've heard from many young women who are now my daughter's generation in baby showers asking, "What can we give babies that's safe?" "You're the green one, tell us." And the truth is we don't know because we don't know what's in the baby products and we'd like that to be disclosed immediately. Right now, our values say to protect creation and protect our most precious resource which is our children. We applaud Washington State for doing that in a really good way and leading the country in doing it but we need to take the next step. We can't continue the experimentation on our children's bodies that's been going on for many years now. We simply need to set limits. In conclusion I want to say that I understand that the chemical industry struggles with regulation but they'll survive the regulation and our children won't.

Bill Alkire

Thank you Angela. My name is Bill Alkire. I'm here representing the Toy Industry Association (TIA). My address is 6020 Butterball Lane NE Olympia, Washington. I will keep my comments very brief tonight. What I'd like to do first and probably foremost is thank the department for its hard, hard work to try to develop a rule that is implementable for the Department of Ecology as well as for the people that will be required to comply with this new regulation. TIA does not agree with all the current language in the proposed rule. However, we have had a very constructive and open dialogue with the department throughout this rule making process and we thank them again for that. We have no specific comments on the draft rule at this time but will provide written comments before the close of business on the 15th of this month. And again, thank you John, Carol and the rest of your team for the work you've done on this rule.

Does anyone else want to provide formal testimony?

If you would like to send ecology written comments, please remember they are due by June 15th, 2011. Send them to:

John Williams

Waste 2 Resources Program

Department of Ecology

PO Box 47600

Lacey, WA 98504-7600

John.williams@ecy.wa.gov

Or fax:

360-407-6102

All testimony received at this hearing along with all written comments received by June 15, 2011 will be part of the official hearing record for this proposal. Ecology will send notice about the Concise Explanatory Statement Publication to everyone that provided written comments or oral testimony on this rule proposal, everyone who signed in for today's hearing that provided an email address and 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 concerns that were raised during the public comment period. If you would like to receive a copy but did not fill out a card, 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 will make a decision about adopting the proposal. Depending the number and type of comments received, adoption is currently scheduled for July 2011. If the proposed rule should be adopted at that time and filed with the code reviser, it will go into effect 31 days later. The first reports required under the rule will be one year from date of adoption. If we could be of further help to

you, please let us know or you can contact John Williams. On behalf of the Department of Ecology, thank you for coming. I appreciate your cooperation and courtesy. Let the record show this hearing is adjourned at 7:50 p.m...