

Children's Safe Product Act Report

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Children's Safe Product Act Report

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Acronyms and Abbreviations

BBP	Benzyl butyl phthalate or butyl benzyl phthalate	
CAS No.	Chemistry Abstract Services chemical ID number	
CHCC	Chemical of High Concern for Children	
CPSIA	U.S. Consumer Product Safety Improvement Act	
CSPA	Washington Children's Safe Product Act	
DBP	Dibutyl phthalate	
DEHP	Di-(2-ethylhexyl) phthalate	
DIDP	Diisodecyl phthalate	
DINP	Diisononyl phthalate	
DNOP	Di-n-octyl phthalate	
DOH	Washington State Department of Health	
Ecology	Washington State Department of Ecology	
EU	European Union	
HPC	High Priority Chemical	
ME DEP	Maine Department of Environmental Protection	
NHTSA	National Highway Traffic Safety Administration	
ppm	parts per million	
PVC	polyvinyl chloride	
XRF	x-ray fluorescence	

Executive Summary

This report describes work done by the Washington State Departments of Ecology and Health to comply with the requirements of the state Children's Safe Products Act (CSPA), address concerns raised by stakeholders, and to implement direction from the Governor.

Key CSPA provisions

The CSPA represents a new approach to reducing risks posed by toxic chemicals in children's products. Rather than addressing problems caused by continued use of toxic chemicals one product or one chemical at a time, this law addresses many chemicals and many products. Under this law, manufacturers of children's products will have to understand what toxic chemicals are in their products and report this use to the Department of Ecology. Examples of children's products covered in this law include toys, jewelry, feeding accessories, and car seats. Certain products are exempt from the definition of children's product, such as chemistry sets, bicycles and tricycles, video toys, consumer electronic products, sporting equipment, and batteries.

The law consists of the following provisions:

- The Department of Ecology is to:
 - Identify high priority chemicals that are of high concern for children, in consultation with the Department of Health.
 - Identify children's products or product categories that contain chemicals of high concern for children.
 - Identify policy options for addressing children's products that contain chemicals of high concern for children, including ways to inform consumers about toxic chemicals in products.
 - Submit a report on chemicals of high concern for children and their presence in children's products or product categories to the appropriate standing committees of the legislature by January 1, 2009¹.
- Manufacturers of children's products must report on their use of high priority chemicals 6 months after Ecology adopts a rule to implement the law.

¹ This report is being submitted 6 months after the stated statutory deadline because of three unanticipated events: the hiring/contracting freeze of 2008; the creation of the advisory group; and the need to adopt a rule to clarify one provision of the law. Ecology had planned, as described in the fiscal note for HB 2647, to hire a contractor to develop the list of chemicals of high concern for children and enable us to meet the January, 2009 report deadline. The 2008 freeze on hiring and contracting meant that the agency staff had to undertake this task. The creation of the advisory group and the need to develop rules diverted staff resources and delayed our ability to complete the report on time.

• The Department of Health is authorized to conduct a product safety education campaign regarding children's products that contain chemicals of high concern for children (CHCCs)².

The law also includes provisions to limit the amount of lead, cadmium and phthalates in children's products, beginning July 1, 2009. However, the passage of new federal legislation (see the discussion on page 11) preempted these standards for most children's products.

Advisory Group to address concerns Stakeholders

This report also addresses a number of concerns raised by various stakeholders. To respond to these concerns Governor Gregoire convened a stakeholder Advisory Group to assist Ecology and DOH in developing practical and common sense approaches to implementing this law. This group met four times between June and October, 2008. Key topics addressed by the Group included:

- Lead standards and federal preemption.
- The list of chemicals of high concern for children.
- The challenges presented by the reporting requirements.

The Advisory Group's primary task was to recommend any needed amendments to the law to ensure that the availability of safe toys in Washington is not adversely affected by implementation of the act. The passage of the federal CSPIA largely alleviated the major concerns of the Advisory Group, who made no recommendations to change state law at this time.

Preemption of the chemical standards in CSPA by federal law

The lead, cadmium and phthalate standards described in CSPA (RCW 70.240.020) were substantially preempted by the passage of the federal Consumer Product Safety Improvement Act (CPSIA) by Congress in August, 2008. This federal act limits the amount of lead, cadmium and phthalates permissible in children's products and explicitly preempts states from enacting or implementing similar legislation. After consultation with the Office of the Attorney General, Ecology decided that pursing an exemption from this federal preemption would likely result in a protracted legal argument with only marginal opportunity to improve the safety of children's products. Therefore, in Washington we are deferring to the CPSIA regarding use of lead, cadmium and phthalates in children's products.

² DOH has created a new website containing information about Children's Health and Safety (<u>http://www.doh.wa.gov/children/</u>). This website contains links to information about recalled children's products and other information and will be used for posting information about chemicals of high concern for children in children's products per the CSPA.

Identifying chemicals of high concern for children (CHCCs)

The CSPA requires the Department of Ecology (Ecology), in consultation with the Department of Health (DOH) to identify high priority chemicals of high concern for children. Six months after Ecology adopts rules to implement the CSPA, manufacturers of children's products must notify Ecology if their products contain high priority chemicals. This part of the CSPA is not preempted by federal statute.

Building upon the work of other jurisdictions, Ecology identified those substances that meet the statutory definition of high priority chemicals. The second step has been to identify which of these high priority chemicals are of high concern for children (CHCCs) by considering a child's potential for exposure to these chemicals. Ecology has identified high priority chemicals that appear to meet the criteria in the law for chemicals of high concern for children.

The agencies are working with the University of Washington to develop a mechanism to prioritize this list. Priority will be based primarily on exposure and toxicity, although consideration must also be given to practicalities such as the availability of testing methods. Several members of the Advisory Group encouraged the agencies to consider the interactions between chemicals and child development as part of this prioritization process.

None of the lists of chemicals described above are being included in this report because work is still on-going to both vet the lists and document the process being used to create and prioritize them.

Stakeholders and the public will have an opportunity to review and comment on the process used to indentify high priority chemicals of high concern for children in the fall of 2009. We anticipate that a final list will be available by spring, 2010. Also, the list of chemicals that trigger the CSPA reporting requirements will be included in the final rule, giving the public one more opportunity to comment.

Since new chemicals are introduced into the market all the time, and new information becomes available about existing chemicals, it will be necessary to periodically add or subtract chemicals from the list.

Identifying chemicals in children's products

In addition to identifying CHCCs, CSPA requires Ecology to report on which of these chemicals are present in children's products. Unfortunately, there is little information available on chemicals in children's products. The Danish EPA conducted a series of studies testing for chemicals in consumer products, including a number of children's products, but it is not clear that those products are representative of children's products found in the U.S. Some product

testing data is available from non-governmental organizations but these studies may not be representative of the U.S. market and rely on a test method that can only identify certain types of chemicals. Ecology and DOH continue to evaluate the available data.

Reporting and testing requirements

The Advisory Group identified a number of CSPA reporting requirement challenges, particularly concerning the costs of compliance. Small manufacturers often do not know what chemicals are present in the materials they use to make their products and suppliers appear to be either unable or unwilling to provide this information. Even large manufacturers sometimes run into this problem. This situation raises a concern that in order to comply with the notification requirements, manufacturers would have to test every product for every chemical on the list. The costs incurred to meet such a requirement could make it uneconomical for some manufacturers to market their products in Washington.

Ecology and DOH evaluated laws from other states and jurisdictions to identify where testing and reporting requirements are already in place. We also examined approaches being used by the private sector to assess chemicals in their products. We concluded that while there are challenges to developing a workable reporting scheme, there are reporting requirements already in use in other jurisdictions or sectors that can be adapted or modified to satisfy CSPA and help mitigate the cost of compliance on manufacturers.

Policy options to address children's products that contain CHCCs

Once the reporting mechanism has been established, Ecology will have to determine how best to use the reported information to inform consumers, reduce the potential for exposure to chemicals of high concern for children, and improve the safety of children's products. There are a number of possible actions Ecology may consider. Many of the options presented are mentioned in California's new Green Chemistry Laws and are included to spur discussion to achieve the goals of the CSPA. A number of these ideas would require additional statutory authority for the agencies to carry out. Ecology and DOH have not explored these ideas in the detail needed to make recommendations.

Availability of safe car seats

Specific concerns were raised about the effect of this law on the availability of safe car seats. The federal preemption applies to some, but not all, car seats. As such, the lead, cadmium and phthalate standards in the CSPA apply only to those car seats not regulated by the CPSIA. Manufacturers of car seats, when contacted, gave no indication that they would pull out of the Washington market if the law remained in effect. Based on these discussions and an assessment

of available information on the presence of lead, cadmium and phthalates in car seats, Ecology and DOH believe that car seats currently marketed in Washington do not pose an imminent threat to children. Therefore, Ecology recommends use of its discretion to delay enforcing these standards until the rule making to implement the CSPA is completed.

Coordination with other states

Ecology and Health are working with other states who are implementing similar legislation. Maine, Minnesota, and Connecticut have laws addressing toxic chemicals in children's products. California has a newly passed law that addresses use of toxics in all consumer products. Oregon and Michigan are currently considering a children's product law as well. All these laws require the identification of high priority chemicals and all have some kind of reporting mechanism. Ecology and DOH are working with these states to coordinate and share information with a goal of developing a set of regulations that work with each other rather than providing a patchwork of different state requirements.

Rule making under the CSPA

Ecology has begun a pilot rule making, per RCW 34.05.313, to test reporting options. Several manufacturers have agreed to participate in this process which includes an advisory committee made of interested stakeholders. Readers interested in this rule making process can track its progress at the following web site:

http://www.ecy.wa.gov/programs/swfa/rules/ruleChildSafe.html. Some members of the Governor's 2008 Advisory Group were asked to participate in this advisory committee as well. A pilot rule is expected by January, 2010. Formal rule making will begin in Spring, 2010.

Key Findings and Conclusions

- 1. Ecology and DOH concluded that with the passage of the federal CPSIA, we currently do not need revisions to the CSPA to meet the goals of the legislation and address stakeholder concerns. If changes to the law are needed to improve its implementation, these changes will be become apparent through the rule-making process.
- 2. The agencies found that the list of high priority chemicals and chemicals of high concern for children can be developed using existing sources of information.
- 3. The agencies recommend that the list of chemicals of high concern for children be updated periodically to reflect new scientific information.
- 4. The agencies found that many chemicals appear to meet the definition of high priority chemicals of high concern for children and that this list needs to be prioritized to identify which chemicals should trigger the reporting requirements. This prioritization should focus on chemicals where exposure to children is likely.

- 5. The agencies found that there are a number of challenges to meeting the reporting requirements and that options to address these concerns can likely be addressed through rule making.
- 6. The agencies found existing testing and reporting requirements that are applicable to children's products may be appropriate for use in complying with CSPA.
- 7. The agencies found that most car seats appear to meet the CSPA standards for lead, cadmium and phthalates, and those safe car seats will continue to be available in Washington. While some car seats are not regulated under the CPSIA and therefore are subject to the CSPA, Ecology should exercise enforcement discretion and forego taking enforcement against car seat manufacturers until rulemaking to implement the CSPA is completed.
- 8. The agencies found that there are opportunities to minimize the costs of complying (for both the regulated community and the state) through collaboration and data sharing with other states.
- 9. The agencies found that implementation of the reporting requirements should result in reductions in the use of toxic chemicals in children's products.

I. Introduction

On April 1, 2008, Governor Gregoire signed the Children's Safe Products Act³ into law. This bill has three major components:

- (1) It limited the amount of lead, cadmium and phthalates allowed in children's products offered for sale in the State of Washington⁴.
- (2) Ecology, in consultation with the department of Health (DOH), is required to identify "high priority chemicals that are of high concern for children." Six months after Ecology develops rules to implement this act, manufacturers of children's products report on their use of high priority chemicals to Ecology.
- (3) The law amended RCW 43.70.660 and authorizes DOH to conduct a product safety education campaign regarding children's products that contain CHCCs.

Although she signed the bill, the Governor also vetoed two sections and noted several issues with the statute:

- Section 1 "could be read to create obligations that are beyond what the state government can deliver."
- "Without careful implementation this bill could adversely affect the availability of safe toys in our state, including important educational toys."
- "We must be absolutely certain this bill will not reduce the safety of car seats."

In her signing message, the Governor signaled her intention to establish an advisory group to work with Ecology and DOH to make sure the bill is implemented with common sense. She asked the group to look at the standards and consider the timelines needed for the industry to implement these new standards. She also asked the committee to develop any needed recommendations for legislation to ensure safe products in a manner that is practical and achievable for the industry. The complete text of the veto message can be found at <u>veto message</u>.

In addition, the Governor directed Ecology to expedite rule making pertaining to internal electronic components of toys. Finally, the Governor noted that as Ecology and DOH move forward with the identifying chemicals of high concern for children they should "focus on the highest priority chemicals... [and] should rely on safety testing conducted in the European Union and California, to the extent they provide a reasonable assurance of safety, in order to help establish a degree of consistency for the industry."

³ Engrossed Second Substitute House Bill 2647

⁴ By July 2009 no children's product could be offered for sale in the state containing (a) lead at ninety parts per million; (b) cadmium at forty parts per million; and (c) phthalates at one thousand parts per million.

This report addresses the issues raised by the Governor in her veto message and fulfills the requirements of RCW 70.240.030(3).

II. Advisory Group and Stakeholder Input

Initial Considerations

From June through October 2008, the Children's Safe Products Advisory Group⁵ met four times. At the first meeting, the group set forth a list of issues it wished to address, as follows:

- Electronic components
- Car seats
- Testing, especially how product testing would align with the European Union and California requirements
- Timelines, including:
 - o Grandfathering of products
 - Impacts of manufacturing cycles on implementation
 - Government enforcement timelines
- List of chemicals
 - Proprietary information
 - Confidential business information
- Issues related to age
- Product exceptions
- Communications with the public

Initial discussions in the Advisory Group revealed that there were several objectives shared in common by all members:

- 1. They want to promote children's safety.
- 2. They want to craft an effective law that will positively affect children's safety.
- 3. They want to create a practical and enforceable law.

Areas of Focus and Discussion Summary

In its second meeting, the Advisory Group heard presentations on a host of subjects including car seats, toy manufacturing and the retail supply chain, chemical standards and use protocols, and testing methods. There was also a demonstration of the x-ray fluorescence (XRF) testing method.

Car Seats

Following the presentation on car seats, the Group reached these conclusions:

• It appears that most car seats will meet the CSPA standards for external surfaces and components.

⁵ A list of committee members follows.

- On balance, safety concerns suggest that internal components that provide structural safety should be exempt from the standards, when a company has exhausted other reasonable alternatives.
- External components meet the standards, with the possible exception of metal buckles, for which there might not be an adequate and currently available substitute.
- The burden of responsibility is on the manufacturers to come forward and report to regulators that removing certain components or materials would compromise safety.
- DOH should continue to pursue information from manufacturers.

Toy Manufacturing and the Retail Supply Chain

Presentations from large manufacturers and small and large retailers provided the Group with an overview of the impacts the CSPA could have from different viewpoints.

From large manufacturers the Group heard:

- The toy industry is made up of 3 to 5 very large companies (such as Hasbro and Mattel) and a very large number of smaller companies.
- Most toys have a short lifespan; about half of all toys currently being sold were introduced within the last 3 years.
- The toy industry is a "trailing edge" technology user in that toy manufacturers do not invent new technologies or materials. Instead, they wait until technologies become generic and adaptable to toys.
- 40% of toys marketed today have at least some electronic or mechanical components.
- Current toy testing requirements are divided into 4 categories: physical, mechanical, flammability and small parts.
- The toy industry needs to balance replacing materials with less toxic options with the long standing concern over minimizing the hazards of small parts.
- The toy design process takes 12 to 18 months from initial concept to production of the final product.
- The Toy Industry Association (TIA) is in the process of developing a new toy safety certification program that will require toy importers and manufacturers to meet three requirements: implement hazard assessment of toy design; conduct factory audits; and conduct product sample testing to validate that the factory is producing toys that meet the standard. These requirements have to be verified by an accredited certification body before the toy will be allowed to bear a certification label. The first toys certified under this standard should be on the shelves for the 2009 holiday season.

Small retailers made the following assertions:

• Small and specialty toy stores are very different from mass-market distributors in that they have personal contact with both suppliers and customers.

- Small and specialty toy stores tend to sell products that have a much longer useful shelf life than the 3 year average that applies to mass-market retailers.
- Many manufacturers specialize, making products only for the mass-market or for specialty retailers, and some of the companies that produce toys for both markets have separate product lines for the two markets.
- Many mass-market retailers stock a large percentage of toys from a relatively small number of vendors while specialty stores handpick specific toys from a much larger set of vendors.

Finally, the Group heard the following from Wal-Mart as a representative of large retailers:

- The company has introduced a toy safety program which every vendor must meet in order to sell their product to Wal-Mart.
- Wal-Mart itself conducts about 200 product tests per day.
- It can take up to two years for a manufacturer to meet these standards.
- Recalled products are removed from shelves within 24 hours.

These presentations stimulated much discussion but the Group did not reach any conclusion regarding the CSPA as a result.

Chemical Standards and Toy Testing Methods

The Group heard presentations on testing methods from two vendors. Subsequent discussion focused on lead, cadmium and phthalate standards and associated testing methods. Since the passage of the Consumer Product Safety Improvement Act (CPSIA) significantly preempts the state standards for these chemicals (see the discussion below), much of the information presented to the Advisory Group in the first two meetings was viewed as less relevant to the concerns related to implementation of the CSPA. Readers interested in the discussion should review the meeting notes available at: http://www.ecy.wa.gov/programs/swfa/rules/ruleChildrenAdvise.html

Rule Making to Address Electronic Components of Toys

In July, 2008, Ecology filed a CR101, a preliminary notice that it intended to undertake rulemaking to carry out direction from the Governor pertaining to internal electronic components of toys. In drafting its rule, Ecology consulted the Advisory Group to develop language that was acceptable to all stakeholders. While there were significant differences on what the scope of the rule should entail, the parties reached agreement on language related to the electronic components of toys as well as a method for determining which toys in the product pipeline could be sold before the statute's restrictions came into play.

Ecology withdrew this preliminary notice after a review of the new federal statute regulating lead in children's products (see below). A comparison of the Washington CSPA law and the federal CSPIA can be found in Appendix 1.

Consumer Product Safety Improvement Act- Federal Preemption

In August, 2008, Congress passed the Consumer Product Safety Improvement Act (CSPIA). This bill amends⁶ the Consumer Product Safety Act, which is the federal statute governing, among other things, the permissible limits for chemicals in consumer products. This new federal statute established different standards for lead, cadmium and phthalates than Washington Children's Safe Products Act and contained language explicitly pre-empting certain state authorities. A comparison of the CPSA and the CSPIA is presented in Appendix 1. The Attorney General's Office reviewed the federal statute and provided an overview to the Advisory Group on the dynamics of pre-emption and various potential effects of this congressional action on the state legislation.

Ecology reported that it had concluded 1) that the chemical standards in the state statute were significantly pre-empted by the federal action and 2) that applying for exemption would likely result in a protracted legal argument with the promise of only minimal improvements in the safety of children's products. Therefore, in Washington we are deferring to the CPSIA regarding use of lead, cadmium and phthalates in children's products. Ecology also concluded that the federal action did not exempt the listing or reporting requirements of the state statute.

After resolving issues related to the CSPIA and federal preemption, the remaining meeting time with the Advisory Group focused on Ecology's proposed approach to identifying chemicals of high concern for children and concerns about the reporting requirements.

Chemicals of High Concern for Children (CHCCs)

Ecology and DOH reported that progress had been made toward identifying chemicals of high concern for children but that the final list would not be completed by the deadline outlined in the statute. The agencies described a basic approach built upon research that other entities have completed including the European Union, the State of California, Canada, the U.S. Federal Government and others. The Advisory Group had a wide-ranging discussion on how the two departments approach the listing process. The departments could:

- Wait for other processes (i.e., U.S. Environmental Protection Agency, European Union, California) to accrue data and then use this information.
- Sort the chemicals into categories (e.g., pesticides, flame retardants) and make reasoned choices of which of those categories likely to involve children's products.

⁶ HR 4040

- Use scientific method as an objective way to add or remove chemicals from the list.
- Select a small, manageable number of chemicals of high concern for the first few years and focus on them, allowing the departments to expand their knowledge of the manufacturing and retail system.
- Rule out certain materials as not being hazardous. Manufacturers should not be required to report on natural toys, for example those made solely of wood, organic cotton or similar materials.
- Consider the potential for exposure when prioritizing the list.
- Consider what happens to children's products upon disposal, after the useful life of the product is over.
- Clarify what risk assessment methods will be used. These methods should take into account the effects of exposure at key points in a child's development, especially when exposure is sustained over several years.
- Consider that very low levels of exposure to some chemicals can harm children.

There was general agreement on the proposed approach to creating the list of CHCCs, but no consensus regarding these suggestions for how Ecology and DOH should proceed.

Reporting Requirements

Finally, the Advisory Group discussed how Ecology could structure the manufacturer reporting requirements of the statute. The discussion covered these subjects:

<u>Confidential business information</u>. An item of concern to the industry from the beginning of the process was whether reporting would expose confidential business information. A particularly telling example would be if manufacturers were required to identify the specific factory that manufactured a toy. Release of this kind of information would be potentially damaging in a competitive marketplace.

<u>Accessibility</u>. Toy industry representatives asserted that there should be an exemption for materials that are not readily accessible insofar as EPA and the European Union provide accessibility exemptions because there is no exposure and little risk. Others members objected to such exemptions on the basis that internal components often become exposed over time, both to children and to the environment in general.

<u>Small manufacturers</u>. There was general agreement that the reporting burden for small manufacturers would be greater than for large manufacturers.

Violations. There was general agreement that Ecology will need to be clear about how it intends to deal with violations of the reporting requirement. There was confusion about how or whether violators would be publicly identified, as well as how or whether the civil penalties in the statute

would be applied. Ecology was also encouraged to employ some kind of testing protocol to assure that manufacturers are in compliance with the reporting requirement.

<u>Communication</u>. Industry representatives in particular urged Ecology to communicate very clearly about the reporting requirements. There was considerable confusion and apprehension in the toy industry about what the reporting might entail, since no other government entity currently requires this kind of reporting for toys. Toy companies will need very descriptive guidance. Medical professionals and health care providers need information to help parents understand that very low levels of exposure can sometimes cause harm to their children.

<u>Changing the list</u>. Some members asserted that Ecology needs to establish a procedure for adding chemicals to the list. At present there are chemicals about which little is known, or where the information is incomplete. The reporting requirement should not preclude adding new chemicals and should include emerging chemicals of concern.

Innovation. Members of the public attending the advisory committee meeting urged Ecology to write the reporting requirements in a way that did not stifle innovation among very small manufacturers.

Conclusions

The Advisory Group did not issue a set of recommendations on the listing and reporting requirements, nor did it indicate that the law should be amended. Members did request that they continue to be consulted as the CSPA rule making proceeds. Some members asked that the Group not be dismissed, but continue to provide advice to the agencies.

Children's Safe Products Act Advisory Committee Members

- Dr. Thomas Burbacher, University of Washington Center of Human Development and Disability
- Representative Mary Lou Dickerson, House of Representatives
- Representative Larry Haler, House of Representatives
- Elizabeth Davis, League of Women Voters
- Carol Kraege, Department of Ecology
- Denise LaFlamme, Department of Health
- Dr. Barry Lawson, Washington Chapter American Academy of Pediatrics
- Senator Debbie Regala, Washington State Senate
- John Ryan, Toysmith
- Dr. Sheela Sathyanaranya, UW Department of Pediatrics
- Jennifer Spall, Wal-Mart
- Laurie Valeriano, Washington Toxics Coalition
- Valla Wagner, Teaching Toys and Books
- Arthur Kazianis, Toy Industry Association

III. High Priority Chemicals and Chemicals of High Concern for Children

Background

The CSPA requires Ecology and DOH to identify high priority chemicals of high concern for children (CHCCs). Six months after Ecology adopts rules to implement the CSPA, manufacturers of children's products that contain high priority chemicals will be subject to the reporting requirement of the rule.

Regarding the development of the list of chemicals of high concern for children, the Governor stated:

"The language in [section 4] could result in a long list of chemicals, and future reporting requirements beyond those needed to ensure the safety of children's products. The department's fiscal analysis of the bill assumed no more than fifty chemicals would be identified, and the Legislature has funded their work accordingly. I ask the Department to focus on the highest priority chemicals, considering good science on the effect of chemicals on the health of children, and those chemicals likely to be found in children's products."

This section describes the agencies' approach to developing the list of CHCCs and presents options for prioritizing this list to identify which of these chemicals pose sufficient risk to warrant reporting when they are found in children's products.

The list of CHCCs is being drafted by Ecology and DOH, but the process to finalize it will be done with input from stakeholders and the public.

Identifying Chemicals of High Concern for Children

The CSPA defines the characteristics of High Priority Chemicals (HPCs), provides guidance regarding acceptable sources of information, and includes criteria indicative of the potential for exposure. To identify High Priority Chemicals of High Concern for Children (CHCCs), Ecology first identified chemicals that meet the definition of a High Priority Chemical. With as many as 80,000 chemicals in use today, we built upon the authoritative work of other jurisdictions to identify which of these chemicals meet the definition of a high priority chemical. New chemicals are introduced into the market all the time and new research is continually being published on the impacts of chemicals already in use. Therefore, the list will be subject to change as new information makes it necessary to either add or subtract chemicals from the list.

The next step has been to identify a subset of High Priority Chemicals that also meet one or more of the criteria in section -030 of the law for chemicals of high concern for children. These criteria provide an indication of the potential for a child to be exposed to particular chemicals.

The final step will be prioritization of this list to identify which chemicals should trigger the reporting requirements found in section -040 of the law. Priority will be based primarily on exposure and toxicity, although consideration must also be given to practicalities such as the availability of testing methods. We also eliminated chemicals from consideration because they are unlikely to occur in children's products. For example, nicotine is a very toxic substance that meets all the criteria to be identified as a CHCC, but nicotine is not added to products marketed to children and therefore should not trigger reporting. Figure 1 is a conceptual depiction of this process.

None of the lists of chemicals described below are included in this report because work is still on-going to both vet the lists and document the processes being used to create and prioritize them. In addition, the advisory committee and the public will be invited to comment on this effort before the final lists are published.

High Priority Chemicals

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

(6) "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.

Table 1 lists the information sources used to identify high priority chemicals. Each source identifies chemicals as having one or more of the characteristics of a high priority chemical as defined by the CSPA. Details on these sources are found in Appendix 2. Ecology relied on reports and research published by state, federal or other governmental agencies as the primary source of information for the task of identifying chemicals that meet the high priority definition. These reports have all been subject to scientific and public scrutiny and are therefore considered "authoritative". In the absence of such governmental reports, Ecology relied on scientific literature if the report or study has been peer reviewed and published in a scientific journal. These practices also provide for scientific and public scrutiny and are considered authoritative.

The agencies turned to other sources (such as unpublished data from non-governmental organizations or industry) only in the absence of more authoritative information.

Ecology has identified more than 1800 high priority chemicals which meet the HPC criteria.



Figure 1. Conceptual approach to identifying chemicals for reporting under the CSPA.

Ecology organized data collected over the past months in spreadsheets and an Access database, with a central goal of making all source information transparent. The volume of information gathered has reached a point where the current database structure is inadequate. In the coming months, as resources permit, Ecology will build a new, more robust database, to better query, manage, and store the volume of data amassed. In the meantime, the agencies have begun using the information gathered to identify chemicals of high concern for children.

Table 1: Sources used to identify high priority chemicals and characteristics of chemicals from these sources

T	Name of agency, program, list or	Toxic effect or characteristic to
Jurisdiction	publication	quality as a HPC
United States		
	U.S. EPA PBT Program	PBT characteristics
	U.S. EPA Integrated Risk Information	Carcinogens, developmental and
	System (IRIS)	reproductive toxicants,
		neurotoxicants, systemic toxicity
	U.S. EPA National Waste Minimization	PBTs and metals of concern
	Program	
	U.S. Department of Health and Human	Carcinogens ^a and reproductive
	Services National Toxicology Program	toxicants
	(NTP)	
States	Washington State's PBT Program	PBT characteristics
	California's Proposition 65 list	Carcinogens and developmental
	_	toxicants
International		
WHO	International Agency for Research on	Carcinogens ^b
	Cancer (IARC)	
Europe	European Union (EU) Substances of very	CMRs ^c , PBT characteristics, vPvB
_	high concern (SVHC) program	
	EU Endocrine Disruptor program	Endocrine disrupters
	EU PBT program	PBT characteristics
	EU Chemicals for risk assessment	Chronic toxicity, especially CMRs
	Oslo-Paris Convention (OSPAR)	Endocrine disrupters, PBT
	Chemicals of Concern	characteristics
	Oslo-Paris Convention (OSPAR) Priority	Endocrine disrupters, PBT
	Chemicals	characteristics (subset of above)
Canada	Canadian EPA PBiT ^d list	PBT characteristics
Other	Grandjean & Landrigan (2006).	Neurotoxicants
	Developmental neurotoxicity of industrial	
	chemicals – a review. The Lancet, 368	
	(9553): 2167-2178.	

^a Includes chemicals classified as known to be human carcinogens and reasonably anticipated to be human carcinogen.

^b Includes chemicals classified as carcinogenic to humans (Group 1), probably carcinogenic to humans (Group 2A) and possibly carcinogenic to humans (Group 2B). Groups 3 (not classifiable as carcinogenic to humans) and 4 (probably not carcinogenic) were not included in this evaluation.

^c CMR = Carcinogenic, mutagenic or reproductive toxicity

^d PBiT = Persistent, bioaccumulative and inherently toxic to human health and the environment

Potential Chemicals of High Concern for Children

Once a chemical is determined to have the characteristics of a HPC, the next step is to determine if that chemical is potentially of high concern for children. The Children's Safe Product Act

provides guidance on how the HPCs must be evaluated to identify CHCCs. The exact language in 70.240.030 RCW states:

(1) By January 1, 2009, the department, in consultation with the department of health, shall identify high priority chemicals that are of high concern for children after considering a child's or developing fetus's potential for exposure to each chemical. In identifying the chemicals, the department shall include chemicals that meet one or more of the following criteria:

(a) The chemical has been found through biomonitoring studies that demonstrate the presence of the chemical in human umbilical cord blood, human breast milk, human urine, or other bodily tissues or fluids;

(b) The chemical has been found through sampling and analysis to be present in household dust, indoor air, drinking water, or elsewhere in the home environment; or

(c) The chemical has been added to or is present in a consumer product used or present in the home.

These criteria are indicators of a child's potential to be exposed to chemicals. Ecology searched the scientific literature and compiled information to identify high priority chemicals that appear to meet these exposure criteria. Credible sources of information are available for each of the following four major areas referenced in the legislation:

- 1. Human Biomonitoring Data
- 2. Indoor Air and Dust Data
- 3. Drinking Water Data
- 4. Product Data

There are no comprehensive studies on all these topics. Details on the sources of exposure indicator information identified to date are included in Appendix 3. Since new information is published every year, this list will need to be updated periodically.

Identifying High Priority Chemicals of High Concern for Children for Reporting

As indicated in Figure 1, chemicals which are identified as high priority and which are also found in one or more of the exposure categories are identified as potential CHCCs. The agencies are considering how best to prioritize this list to identify High Priority Chemicals of High Concern for Children (CHCCs). Chemicals identified as such will trigger the reporting requirement if they are present in children's products.

Ecology has entered into an agreement with the University of Washington (specifically Dr. Catherine Karr, Assistant Professor of Pediatrics, Adjunct Assistant Professor, Environmental

and Occupational Health Science) to help evaluate and screen prioritization methods and procedures.

There are many ways that children can be exposed to hazardous chemicals in their environment. They can be exposed to chemicals through food and drinking water, through indoor and outdoor air, through ingestion of dust and soil, and through direct contact with products they use and products used in their home. Evaluating children's exposures typically considers the ages and activity patterns of children, the pathways and sources of exposures, and information on the frequencies, levels and routes of exposures.

Understanding exposures from the variety of children's products included in the CSPA will be a complex exercise. Assessing exposures from children's products includes understanding which products contain which chemicals, the ages of children using these products, how the chemicals might migrate out of the products or otherwise be available to children, and how much of the chemicals would be absorbed into children's bodies. Since the CSPA applies to a wide variety of products (toys, clothing, feeding and sucking supplies, jewelry, car seats), the agencies will consider exposures from all of these types of products.

Ideally, the types of exposure and hazard-related data that should be considered in prioritizing Chemicals of High Concern for children would include answers to the following questions:

- How much of the chemicals are used in children's products?
- How prevalent are children's products containing the chemicals?
- What is the likelihood of exposures from children's products?
- How many children are likely to be exposed?
- What are the ages of children using products containing the chemicals?
- Where are the chemicals used in children's products, i.e. are they accessible?
- How do children interact with the materials in which the chemicals are used?
- Are there other significant sources of exposures to the chemicals?
- What is the amount of exposure, i.e., potential dose level?
- What is the frequency and duration of exposure?
- What is the likelihood of adverse health effects from exposures through children's products? (combining toxicity and exposure information)
- What are the uncertainties associated with estimating exposures to different chemicals?

For many chemicals the agencies expect that there will be limited data available to answer these questions. This is mainly due to limited information about the quantities, prevalence and accessibility of chemicals in children's products. The Danish EPA, however, has done considerable work on chemicals in products with specific attention to products geared toward children. Their work includes a hazard assessment of some products which might prove useful in this process (see chapter VI and Appendix 3).

There are several concerns associated with the Danish work including questions about the number of samples tested, whether or not the toys sampled in Denmark are the same as toys sold in the U.S., the rapid changes in the toy market, etc. However, information on chemicals in toys from an unbiased, authoritative source is extremely limited. 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.

As with other data needs related to implementing the CSPA, the agencies are building upon the work of others. There are existing guidance documents (see Appendix 4) that describe methods for estimating exposures among children from various media. The agencies will consult these reports in determining how best to assess exposures for prioritizing CHCCs. Ecology and DOH continue to collect and review other relevant publications to help address exposure-related issues related to children's products.

Options for Prioritizing Chemicals of High Concern for Children

A number of policy options should be explored during the rule-making process to achieve the goals of the Children's Safe Products Act and to address the concerns of the stakeholders. The intent of all these options is ultimately to focus the reporting and testing requirements (see Chapter IV) on those chemicals that pose real threats to children. A number of these options were suggested by the Advisory Group.

Lower priority could be given to chemicals that are:

- Not intentionally added to materials or components of children's products.
- Regulated under existing Federal regulations.
- Emerging chemicals of concern (i.e. those chemicals where toxicity testing data is still emerging).

Higher priority consideration could be based on one or more of the following criteria:

- Toxicity.
- Demonstrated presence in children's products.
- Availability of a suitable test protocol.
- Exposure potential and amount of exposure.
- Age of children potentially exposed.
- Availability of safer alternatives.
- Amount of the chemical in commerce.
- Prevalence of the chemical in materials commonly used in children's products such as plastics or additives to cosmetics.

To facilitate this effort, the agencies, in conjunction with the University of Washington, are evaluating existing prioritization schemes developed by other authoritative agencies and which may prove applicable. References for these prioritization schemes can be found in Appendix 4.

In general, the prioritization methods listed in Appendix 4 integrate information about toxicity and exposure to derive a final ranking or priority. For example, the method used by Health Canada to prioritize their domestic substances list for human health includes toxicity information in addition to information about chemical use and estimated human exposures.⁷

Related Activities in Other States

Ecology and DOH have made good progress toward identifying high priority chemicals of high concern for children, but much work remains. Several other states are working to implement similar laws or are otherwise involved in developing lists of chemicals similar to the chemicals of high concern for children. It will benefit businesses and citizens if these states can collaborate on developing consistent lists. A summary of relevant laws passed in California, Connecticut and Maine are presented in Appendix 5.

⁷ K. Hughes, Health Canada, 2007. Prioritization of existing substances under the Canadian Environmental Protection Act. Powerpoint presentation presented at OEHHA-COEH workshop on practical decision-making tools for identifying safer alternatives, Sacramento, CA, Oct. 1-2, 2007. Available at: http://oehha.ca.gov/multimedia/green/coeh100107.html

IV. Reporting and Testing Requirements

Background

Children's product manufacturers and retailers raised two major concerns regarding the reporting requirements in the Children's Safe Product Act. First, some said that manufacturers do not know the chemical composition of their products and would be unable to determine it given the lack of information communicated through their supply chain. Second, they state that third party testing to determine chemical content would be prohibitively expensive, especially for smaller manufacturers and for multiple chemicals.

In considering these concerns, Ecology and DOH reviewed existing reporting requirements in place in Washington and in other jurisdictions, to determine if compliance with these requirements can satisfy all or part of the CSPA. The agencies also reviewed actions taken by manufacturers themselves in order to better understand and communicate the chemical content of their products.

Existing legislation

Manufacturers of children's products already comply with restrictions on chemical use and reporting requirements in other jurisdictions. While none of the existing laws and regulations are exactly like the Children's Safe Product Act with respect to reporting, information generated to comply with existing requirements could be used to help fulfill reporting requirements of the CSPA, depending on how the requirements are designed during the rule making process.

Below is a summary of several laws that are relevant to this discussion.

Toxics in Packaging

The Toxics in Packaging model legislation, intended to reduce the presence of heavy metals in packaging materials was passed in Washington in 1991. As of July 2004, similar legislation has been adopted by eighteen other states.⁸ Specific provisions vary from state to state; however, compliance mechanisms generally consist of a written self-certification that the packaging meets the requirements of the act. In Washington's legislation, the certification must be maintained by the packaging manufacturer and must be provided to Ecology upon request. Enforcement occurs through inspection, sampling and records review.

The Toxics in Packaging legislation in many other states includes details not found in the Washington legislation. Many states, including California, provide an exemption for recycling up to a certain level. If the presence of the metals in the packaging is incidental to manufacture (i.e.

⁸ <u>http://www.toxicsinpackaging.org/adobe/TPCH-fact-sheet.PDF</u>

found due to the use of recycled materials), the packaging can be sold only if the metals are present at levels below a total of 100 ppm. Manufacturers, therefore, can only comply with these provisions if they have knowledge of what metals are in the packaging they use. Further exploration of how manufacturers comply with these requirements is needed.

California's Toxics in Packaging legislation contains further exemptions. For specific types of packaging, an exemption is included for packaging that contains metals in order to meet health and safety requirements for certain products. Packaging for which there is no alternative ingredient to the metal is also exempted. In these cases, the California Department of Toxic Substances Control (DTSC) has required "detailed information" concerning the necessity of adding the metal and describing efforts to seek or develop alternatives to eliminate the metal. The rule making for the CSPA could explore requiring a statement from manufacturers describing alternatives in the discussion of the chemical functions.

Interstate Mercury Education and Reduction Clearinghouse

The Interstate Mercury Education and Reduction Clearinghouse (IMERC) is associated with the Northeast Waste Management Officials Association (NEWMOA). IMERC was launched by NEWMOA in 2001 in response to legislation by states in the Northeast and other parts of the country focused on reducing mercury in products and waste. One common element of mercury legislation in other states is a requirement for manufacturers of certain products containing mercury to register those products, along with the volume of mercury they contain. Because these provisions are, in large part, consistent among states, manufacturers are able to complete one form, developed by IMERC, duplicates of which are submitted directly to the states that require the information. Once the states have removed any confidential business information, the information is forwarded to IMERC. IMERC posts the information in a searchable database on its website, providing a single point of contact for both the public and manufacturers. The IMERC state members include California, Connecticut, Illinois, Louisiana, Maine, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Rhode Island, Vermont, and Washington.⁹

Emerging Consumer Product Protection Laws

There are now a few states (Washington, California, Maine, Minnesota and Connecticut) that have laws in place to address toxic chemicals in consumer products and there are several other who are considering similar bills in their respective legislatures. Ecology is working with these states to explore how an interstate clearinghouse could serve a purpose similar to the IMERC.

⁹ http://www.newmoa.org/prevention/mercury/imerc/about.cfm

California Proposition 65¹⁰

California's Safe Drinking Water and Toxic Enforcement Act of 1986 is commonly referred to as Proposition 65 or Prop 65. The law is intended to protect California citizens and the state's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm and to inform citizens about exposures to such chemicals. There are currently more than 700 unique substances and classes of chemicals on the Prop 65 list. Businesses are responsible for determining whether their products contain a listed chemical at a level above a "safe harbor" limit. Businesses must affix a warning label on any product that contains one or more listed chemicals over safe harbor limits; labels do not necessarily specify which chemicals are present or at what levels.

Proposition 65 imposes no obligations on manufacturers to submit any information to a regulatory agency, and thus does not provide guidance on structuring a reporting requirement. However, testing already conducted by manufacturers to comply with Proposition 65 could potentially be used to help comply with the CSPA.

California Safe Cosmetics Act¹¹

The Safe Cosmetics Act, passed in 2005, requires companies that manufacture cosmetics to report the presence of any chemical which appears on one of several lists of toxic substances. The California Safe Cosmetics Act depends heavily upon those chemicals identified in the Prop 65 list (described above.) The California Department of Public Health is developing an online reporting system to manage these required disclosures. With the exception of information that is deemed trade secret information, the submitted information will be made available to the public through this online database.

Small to medium businesses are exempt from these reporting requirements. A manufacturer of a cosmetic product is required to report "if their total annual sales of cosmetic products, both within and outside of California, exceed \$1 million."

The reporting requirement in this law is quite similar to what is required by the CSPA for manufacturers of children's cosmetics. Ecology and DOH will be able to evaluate and learn from California's experience in developing a reporting scheme for a large set of chemicals (783 unique substances).

¹⁰ Official California Legislative Information, <http://www.leginfo.ca.gov/index.html>, <u>http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=58617223856+0+0+0&WAISaction=retrieve</u>

¹¹ http://www.cdph.ca.gov/programs/cosmetics/Pages/faq.aspx

Federal Consumer Product Safety Improvement Act (CPSIA)

The CPSIA will impose testing and auditing requirements upon manufacturers of consumer products. It achieves compliance through certificates that demonstrate that third-party testing has been conducted on a product. The certificate must accompany the product shipment and be furnished to distributors and retailers. Electronic versions of certificates are allowed. No information is reported to the Consumer Product Safety Commission (CPSC) except by request.¹²

Several issues that the CPSC is currently studying should also be considered in the implementation of the reporting requirements of the CSPA¹³, including:

- Criteria for accrediting laboratories that perform testing.
- Required frequency of testing and certification.
- Guidelines for distinguishing product lines (i.e. how to test variations in color or size)

Due to a number of concerns raised as the deadline for implementation of the CPSIA approached (February 10, 2009), the Consumer Product Safety Commission extended the deadline for testing and certification for another year. How the CPSC addresses these challenges will be instructive during rulemaking under the CSPA.

European Union

The European Union (EU) has many directives that impact children's products. On December 18, 2008, the European Parliament adopted a proposal to substantially strengthen current rules on toy safety. This new law eliminates the use of CMR chemicals (those that are carcinogenic, mutagenic or toxic for reproduction) in the accessible parts of toys. It also reduces the allowable amounts of several metals and some very toxic metals, such as lead, may not be added intentionally at all. Finally, this new law requires manufacturers to conduct safety assessments, including information on use of chemicals, and provide this information to authorities. Other European laws that influence the safety of toys include the Toy Safety Directive (TSD) 88/378/EEC, the Restriction on the Use of Certain Hazardous Substances (RoHS) Directive 2002/95/EC, Cosmetic Directive 76/768/EEC, and Phthalates Directive 2005/84/EC. The EU has also new legislation on chemicals, <u>Registration, Evaluation, and Authorization of CHemicals</u> (REACH). All of the directives have specific exceptions. Details on some of these European laws can be found in Appendix 6.

¹² <u>http://www.cpsc.gov/ABOUT/Cpsia/faq/elecertfaq.pdf</u>

¹³ <u>http://www.bureauveritas.com/wps/wcm/connect/bv_com/group/home/news/did-you-know-that/cpsia_hr4040_faq?presentationtemplate=bv_master/news_full_story_presentation/</u>

Toys that are in compliance with the applicable directives carry the CE mark. The CE mark is not specific to toys, and can be used on any product that meets applicable directives for those products. Products may be certified by an independent testing laboratory, which is referred to as a Notified Body, or they may be self-certified by the manufacturer. Trade associations and testing laboratories have screening methods to determine which of the substances are likely to be present in a given product and which tests need to be done to assure compliance. Products that carry the CE mark need to be evaluated to determine if the procedures to obtain the mark can either be adapted for CSPA compliance or can be used to qualify a product for an exemption from reporting.

The European Union's REACH directive is intended to place more responsibility upon manufacturers and importers of chemicals "to manage the risks from chemicals and to provide safety information on the substances."¹⁴ REACH provides a direct analog in some respects to the reporting requirements contained in the CSPA, in that manufacturers and importers of chemicals must register these substances with the European Chemicals Agency (ECHA). This registration includes a dossier on the chemical that details how they have identified and managed risks associated with the chemical they import. This information must also be provided to downstream users of the substances in order to allow these users to manage the substances safely.¹⁵ In addition, REACH will eventually include an authorization system under which companies must justify their continuing use of substances of very high concern. To date, the EU has identified 16 chemicals of very high concern.

Another mechanism of interest is the REACH Substance Information Exchange Forum (SIEF).¹⁶ The objective of this forum is to avoid duplicative animal testing for toxicological purposes. Regulated entities are required to submit the results of vertebrate animal tests and to utilize the results in the forum before conducting additional vertebrate animal tests. This concept of an information sharing forum could be extended to the CSPA by including mechanisms by which companies may share testing data on common components or substances used in children's products.

Private Sector Approaches

In addition to regulatory approaches, some manufacturing sectors have independently put practices into place to help them understand what chemicals are in the products they make. Below is a summary of the two general approaches being used and a brief discussion of how these approaches might be employed as part of implementation of the CSPA.

¹⁴ <u>http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm</u>

¹⁵ http://reach.jrc.it/about reach en.htm

¹⁶ http://www.reach-compliance.eu/french/compliance/SIEF/SIEF.html

Supply Chain Management

In this approach, manufacturers work with their suppliers to specify substances prohibited in component parts or to require information on levels of specified substances in component parts. The CSPA notification requirements specifically allow trade associations to report chemical use on behalf of their members which may help some manufacturers of children's products reduce the cost of compliance.

Following are examples of different industry sectors that collaborated to standardize reporting in their supply chains, including:

- Electronics manufacturers collaborated through the Electronic Industries Alliance, the Japan Green Procurement Survey Standardization Initiative, and JEDEC, which is a developer of standards for the solid state industry, to develop the "Joint Industry Guide: Material Composition Declaration for Electronic Products." The Joint Industry Guide provides suppliers a consistent list of substances for disclosure, reporting thresholds, and reporting format.
- The Global Automotive Stakeholders Group, comprised of representatives from the automotive, automotive parts supplier and chemical and plastics industries, developed the Global Automotive Declarable Substance List to facilitate communication and exchange of information regarding the use of certain substances in automotive products through the supply chain.¹⁷
- The Soap and Detergent Association (SDA), the Consumer Specialty Products Association (CSPA), and the Canadian Consumer Specialty Products Association (CCSPA) developed an ingredient communication initiative as a way to provide consumers with information about the ingredients in products in four major categories: air care, automotive care, cleaning, and polishes and floor maintenance products. This initiative provides different means to inform consumers about the ingredients in products: on the product label; on the manufacturers', distributors', or importers' website; through a toll-free telephone number; or through some other non-electronic means.18
- The Global Data Synchronization Network (GDSN) is in the process of developing standards for manufacturers to report chemical ingredients of their products to a central database, thus improving and standardizing information flow through the supply chain from manufacturer to retailer. Participants in the effort include WalMart, Proctor and Gamble, 3M, Johnson and Johnson, the Consumer Specialty Products Association, the Grocery Manufacturers Association, and the Soap and Detergent Manufacturers Association, among others.

¹⁷ (<u>http://www.gadsl.org/</u>)

¹⁸ (<u>http://www.cleaning101.com/about/11-24-08.cfm</u>)

Numerous other manufacturers maintain restricted substances lists, part of the contractual obligation in place between the manufacturer and its suppliers. These include Glaxo Smith Kline, H&M, Levi Strauss, Nike, SC Johnson, and Shaw Carpets.

Beyond restricted substances lists, some manufacturers have committed to understanding all substances in their products to a level of 100 ppm through product and process design. True Textiles, which manufactures commercial interior fabric, and Herman Miller, which manufactures office furniture, have both designed products to replace undesirable substances with safer alternatives and to provide the manufacturers with full knowledge of substances contained in their products.

Screening Methods

In this approach, manufacturers test their products for the presence of specific substances. Third party testing laboratories currently offer this service to children's product manufacturers, among others, to ensure compliance with regulations in other jurisdictions, including California and the European Union. Conversations with lab staff indicate that the first step is to identify a limited number of substances to test for, based on the composition of a product. For example, a wood toy would not be tested for plasticizers. Manufacturers use knowledge of the production process to identify chemicals likely to be found in their products which are then tested for these substances. If results indicate that substances are present in volumes above a regulatory threshold, the full results are reported to the manufacturer. If substances are all below regulatory threshold levels, the manufacturer simply reports that the product is in compliance.

To gain more complete knowledge about substances contained in their products, manufacturers could request full results of all tests performed and the rationale for not performing other tests.

Reporting Requirement Options

The above review suggests a number of reporting options that could be considered both to achieve the goals of the Children's Safe Products Act and to address concerns of children's products manufacturers and retailers.

The following are options to be discussed with stakeholders and considered during rule makingthey are not recommendations.

- Establish reporting requirements based on the size of the manufacturer
- Exempt manufacturers from the reporting requirement if they make a:
 - Demonstration that the presence of the chemical is incidental or is due to the use of recycled material.
 - Onetime demonstration that the product contains less than *de minimis* levels of the chemical.

- Allow the use of self-certification.
- Allow or adapt the tests/reports done to demonstrate compliance with laws such as the California Safe Cosmetics Act to be used to demonstrate compliance with CSPA.
- Allow some manufacturers to report levels of chemicals of concern by documenting their supply chain. For example, if a small manufacturer makes an unpainted toy out of wood, he or she could make a onetime demonstration of this fact and then be exempted from future reporting requirements if he does not make any substantive changes to his product line.
- Exempt some materials, for example, plain wooden toys, from reporting requirements.

Other options to address concerns of stakeholders include:

- Phasing in the reporting requirements for chemicals of high concern for children. Initially require reporting on a small number of chemicals of greatest concern based on toxicity and exposure. Additional chemicals would be phased in over a period of years. Lead time would be provided for manufacturers to discover whether a chemical of concern was in their product, allowing for potential redesign.
- Phase in reporting requirements by component material. For example, reporting on chemicals of concern related to plastics might be required initially, followed by chemicals of concern in dyes, metals, paints, etc.
- Phase in which manufacturers are required to report by size of manufacturer. Larger manufacturers would be required to report first, followed over a period of years by categories of smaller manufacturers similar to what is being done in the EU under REACH.
- In coordination with other states, provide support to the children's product manufacturing sector to standardize reporting on chemical content within supply chains.
- Work with manufacturers and third party laboratories currently performing testing for compliance with REACH and California's Proposition 65 to increase the amount of useful information from the testing process for manufacturers.

All of these options, plus others to be determined, will be addressed in the rule-making process.
V. Rule Making to Implement the CSPA

Ecology expects to begin rule making to implement the CSPA in the summer of 2009 and is considering conducting a pilot rule making, per RCW 34.05.313, to test reporting options. This approach is only feasible if there is support and willing participation from the regulated community. If such willing partners can be found, Ecology anticipates convening a small advisory committee to assist in the pilot rule making. Some members of the Governor's 2008 Advisory Group may be asked to participate in this advisory committee as well.

The purpose of a pilot rule is to find the most effective way to implement the requirements of the CSPA. It includes a process for testers to easily document issues that arise during testing as well as a process to terminate the test.

Before Ecology can file a formal notice of proposed rule-making (CR-102) for the final rule, the agency will have to prepare a final report that describes the following:

- Any difficulties small business had in complying with the pilot rule.
- A list of recommended revisions to the rule to make compliance with the final rule easier or to reduce the cost of compliance.
- A explanation of the options considered to resolve these difficulties including recommendations from the pilot test group.
- Steps the agency took to include small businesses in the pilot project.

The pilot rule process is now underway and final rule making will likely begin in summer, 2010. If the pilot test reveals the need to amend the act, such changes could be sought during the 2011 legislative session and before the final rule making commences.

VI. Chemicals in Children's Products

Section -030 of the CSPA requires Ecology to evaluate what chemicals of high concern for children appear in children's products. Specifically, RCW 70.240.030(2) states:

By January 1, 2009, the department shall identify children's products or product categories that may contain chemicals identified under subsection (1) of this section.

Unfortunately, little information is available on the presence of chemicals in consumer products. With the exception of cosmetics, manufacturers of most children's products are not required to understand or reveal the chemicals used in their products. To date, the agencies have identified two sources of data on chemicals in children's products.

Danish EPA

One of the best sources of information appears to come from the Danish Ministry of the Environment (Danish EPA), who produced several reports about chemical substances in a variety of consumer products including children's products.¹⁹ For many of these studies, the Danish EPA went into the marketplace, purchased consumer products of interest and analyzed the products for chemicals of concern. They also conducted off-gassing or leaching studies on many of the products and included these results in their reports. The purpose of this product testing was to identify potentially problematic chemicals in products to help improve regulation of these products within the EU. Ecology and DOH are currently reviewing these studies but we have not yet determined if they are representative of products sold in the U.S. 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.

Product testing by the Danish EPA (See Appendix 3 for specific references) included the following products:

- Cosmetics for children.
- Perfume in toys and children's articles.
- Liquid hand soaps.
- Tents and tunnels for children.
- Shoe care products.
- Surface treated wooden toys.
- Textile colorants.
- Glass and porcelain colors.
- "Slimy" toys.
- Kohl and henna products.

¹⁹ Listing and access to reports available at: <u>http://www.mst.dk/English/Chemicals/Consumer_Products/Surveys-on-chemicals-in-consumer-products.htm</u>

- Toys for animals.
- Dandruff shampoos.
- Lip care products with fragrance and flavor.
- Toys and childcare products produced from foam plastic.
- Consumer products impregnated with fluorinated substances.
- Essential oils and fragrances.
- Hobby products for children.
- Jewelry.
- Artificial nails and nail hardeners.
- Baby products.
- Exotic wood products.

The Ecology Center

There is some data available from the Ecology Center, a Michigan-based nonprofit environmental organization. They test toys, compile toy testing data from other groups and publish this data on their website, HealthyToys.org. As of December 9, 2008, the website reports testing data for more than 1,500 toys and children's products for antimony, arsenic, bromine (to indicate brominated flame retardants), cadmium, chlorine (to indicate PVC plastic), chromium, lead, mercury, and tin. Products are tested using XRF technology which measures the presence of elements on the surface of products. The data published by the Ecology Center may not be representative of toys and other children's products available nationally, but it is one of only a few sources of this information. As with the Danish studies, information from the Ecology Center is useful as an indicator of the use of chemicals in products, rather than as a confirmation of the presence of these chemicals in children's products. Information from The Ecology Center will only be used if no other information is available. Details on product testing by the Ecology Center can be found in Appendix 3.

Chemical information collected as part of current regulations

Manufacturers of children's product sold in the various jurisdictions, including the U.S., are required to comply with standards for certain chemicals in their products. These standards are summarized in Chapter IV and Appendix 6. Manufacturers have to determine the presence of certain chemicals in their products in order to comply with these standards, but they rarely have to report such that state agencies or consumers have access to the information. If general compliance with these laws can be confirmed, we may be able to infer that these regulated chemicals are not present in children's products. For example, if a manufacturer can demonstrate that their product is sold in Europe, it may be possible to also assume that that product does not contain any of the chemicals banned in Europe. The agencies will continue to evaluate this premise.

VII. Use of Reported Information – Policy Options

The CSPA lays out the requirements for this report. RCW 70.240.030(3) states:

The report shall include policy options for addressing children's products that contain chemicals of high concern for children including recommendations for additional ways to inform consumers about toxic chemicals in products, such as labeling.

Once the reporting mechanism has been established, Ecology will have to determine how best to use the reported information to inform consumers, reduce the potential for exposure to chemicals of high concern for children, and ensure the safety of children's products. There are a number of possible actions Ecology may consider. Many of the options presented below are mentioned in California's new Green Chemistry Laws and are included to spur discussion to achieve the goals of the CSPA. A number of these ideas would require additional statutory authority for the agencies to carry out. Ecology and DOH have not explored these ideas in the detail needed to make recommendations.

Require additional information

• In cases where an alternative to a chemical of high concern for children is in use, it would not be unusual for the agencies to have little or no information about it. Authority to ask for such information could help the agencies determine if the alternative is safer. Ecology might also ask for additional information on a chemical's use, accessibility by children, or toxicity. Ecology could request an alternatives assessment from manufacturers to determine whether a safer, effective alternative is available.

Increase public awareness

- Beyond what the CSPA already requires DOH to do to educate consumers about the presence of chemicals of high concern in children's products, the agencies might develop and publish a web site that provides consumers with information on the chemicals used in children's products, the reason the chemical has been identified as a high priority chemical, and any safer alternatives to the chemical.
- Require labeling. Labeling is possibly the most direct method of communicating hazard to consumers. However, labeling is expensive and can lead to "warning fatigue" in that if warning labels become too common they are overlooked and do little to prevent exposure.

Restrict chemical use

- Restrict the use of the chemical. Use could be restricted in specific types of products or by amounts permitted for specific uses.
- Prohibit the use of the chemical. Use could be banned in specific types of products.

• Control access to limit exposure to the chemical. Chemicals could be required to be contained in some way or prohibited in products where the chemical's presence would pose particular risk to the intended user.

End of life management

• Require the manufacturer to manage the product at the end of its useful life. This approach may also provide an incentive to the manufacturer to design products with fewer hazardous substances in a way that allows the product to be more easily recycled. This approach would likely only be practical for some subset of children's products, for example, electronic games.

<u>Green redesign</u>

- Ecology could make available grants to universities, private firms or others to develop alternative chemical formulations for children's products that greatly reduce or eliminate risk to human and environmental health.
- Require the manufacturer to fund green chemistry or redesign efforts if no alternatives exist.

VIII. Car Seats and the Children's Safe Products Act

Stakeholders raised specific concerns that the availability of safe car seats, defined as a children's product in the CSPA, could be negatively impacted by the implementation of the law. Like other children's products, car seats are subject to the standards for lead, cadmium and phthalates defined in Section -020 unless the standards are preempted by the CPSIA. In addition, car seats are subject to the reporting requirements for high priority chemicals required in Section -040 of the CSPA.

Federal regulation of car seats under NHTSA

At the federal level, all car seats are regulated by the National Highway Traffic Safety Administration (NHTSA) under the National Traffic and Motor Vehicle Safety Act of 1966, as amended (the Safety Act, 49 U.S.C §§ 30101-170). The U.S. standards for child restraint systems specify requirements for car seats including safety testing methods and certification, specifications for equipment in cars to accommodate car seats, labeling requirements, and recall procedures.²⁰ NHTSA also tracks traffic-related statistics including child injuries and car seat use.²¹ States have enacted various laws mandating car seat use among infants and children.²² Information about car seat requirements in Washington State is available at: http://www.childprofile.org/hpmats/insert/boosterseat.pdf.²³

Federal Preemption

The U.S. standards for child restraint systems (49 CFR Part 571.213) established pursuant to the Safety Act and administered by the NHTSA do not appear to preempt the state lead, cadmium and phthalate standards because these federal standards don't address the same type of risks as those in the CSPA, i.e. risks from exposure to chemical contaminants. However, according to representatives from the Juvenile Products Manufacturers Association (JPMA) who spoke with Ecology and DOH staff, many car seats would be subject to the CPSIA because they are hybrid multi-use products that can be used as car seats and infant carriers either alone or as part of stroller systems. The CPSC and the NHTSA have joint jurisdiction over the regulation of hybrid multi-use products that include a car seat component. Therefore for many car seats, the CSPA

²⁰ Standard No. 213; Child restraint systems. 49 CFR Part 571.213.

²¹ See NHTSA's Traffic Safety facts on Children and Crashes, 2006. Available at: <u>http://www.nhtsa.dot.gov/portal/site/nhtsa/menuitem.9f8c7d6359e0e9bbbf30811060008a0c/</u>

²² Key provisions of state occupant restraint laws through July 1, 2006. Available at: <u>http://www.nhtsa.dot.gov/people/injury/occupant_restraints_chart-4-3-06.pdf</u>

²³ Washington state car seat law available at:

http://www.800bucklup.org/parent/images/PrimaryEnf.SeatBeltLaw.pdf

standards for lead, cadmium, and phthalates would be federally preempted by the federal CPSIA of 2008.

Lead, cadmium and phthalates in car seats and compliance with the CSPA

Governor Gregoire asked the Advisory Group to look at how the CSPA would affect car seat safety and availability. Stakeholders raised concerns about the possibility that car seats would not comply with the new CSPA lead, cadmium and phthalate standards, thereby limiting the availability of compliant car seats available to Washington consumers.

To address this concern, Ecology and Health asked car seat manufacturers and manufacturing associations if they would have problems meeting the new lead, cadmium and phthalates standards. In addition, the agencies requested any testing data on products to assess the actual levels of lead, cadmium or phthalates in car seats. Much of the following information was collected and presented to the Advisory Group before the agencies discovered that many car seats would also have to comply with new federal CPSIA.

Ecology and Health contacted the four largest U.S. car seat manufacturers (Evenflo Company, Inc.; Dorel Juvenile Group, Inc.; Graco Children's Products, Inc.; and Britax USA) and the trade organization that represents them (The Juvenile Products Manufacturers Association (JPMA). The agencies also contacted two Washington state car seat manufacturers (Sunshine Kids Juvenile Products and Prorider).

Dorel Juvenile Group, Inc., the largest U.S. car seat manufacturer, reported that they have been testing for phthalates and that alternatives are available, but cost could be an issue. They also reported that they typically do not use paint or vinyl containing lead and that they were currently evaluating all components for cadmium; however they were not sure if they could meet Washington's lead and cadmium standards. Two car seat manufacturers (Graco and Evenflo) indicated that they were working with JPMA to provide a response to our questions about compliance and testing data. Britax initially provided feedback that they saw no problem complying with our new standards; however, they did not respond to a follow-up question about the use of solder in metal parts. Prorider reported that they had no lead in their base or covering materials. Sunshine Kids Juvenile Products did not respond to questions about compliance or testing.

Feedback from Mike Dwyer, Executive Director of the JPMA, indicates that there is ongoing testing for lead and cadmium in metal car seat components. Manufacturers are indicating to the JPMA that metal structural and component parts will not meet the standards because of trace lead and cadmium that may be present in steel due to the forging and/or recycling process. Mike Dwyer's response from the JPMA indicates that there would be "great cost" associated with

specifying further processed steel, although he does not provide an estimate of this extra cost. He also reports that lead and cadmium do not appear to be a problem in other car seat parts such as plastics, labels, fabrics and coatings.

Despite requests for testing data, none of the car seat manufacturers provided the agencies with laboratory testing results with which to assess actual levels of lead, cadmium or phthalates in products. Based on the information collected from car seat manufacturers it appears that some car seats may not comply with the lead and cadmium standards. However, without specific testing data to evaluate levels of lead and cadmium in car seat parts, or information about how many car seats currently sold would not comply, the agencies cannot predict how the car seat market would be impacted by the new CSPA standards.

Car seat testing data - 2007 and 2008 Ecology Center reports

In 2007 and 2008, the Ecology Center tested car seats for twelve elements including lead, chlorine, bromine, cadmium and mercury.²⁴ As described previously, The Ecology Center is a nonprofit environmental organization based in Ann Arbor, Michigan. A total of sixty-three car seats in 2007 and seventy car seats in 2008 were tested. Car seats were purchased from major retailers for the 2007 testing and from major retailers and some small specialty stores for the 2008 testing. Ten different brands of car seats were tested in 2007 and twelve brands were tested in 2008. Infant and convertible car seats and booster seats were included in the testing. Testing focused on parts of car seats that could come into contact with children or that would be exposed to UV light. The parts of car seats tested included: seat, base, arm rest (2008 only), front strap clip, shade, EBS (expanded polystyrene) foam, and trim (2007 only). All testing was done using an x-ray fluorescence (XRF) analyzer.

The results of lead testing indicate that 19 out of 65 (29%; 2007 data) and 19 out of 70 (27%; 2008 data) car seats contained lead. Of the 19 car seats that contained lead in the 2007 testing, 7 contained lead above 90 ppm (the CSPA standard for lead) in at least one component. For 2008, nine of the 19 car seats containing lead had levels above 90 ppm. The parts containing lead greater than 90 ppm were the seat (9 car seats), shade (6), trim (1) and vinyl fabric (1).

One common problem with measuring lead using an XRF analyzer is interference from other elements. Thirteen of the 19 car seats found to contain lead in the 2007 testing also contained high levels of bromine, most likely from the use of brominated flame retardants. In these seats, the lead concentrations measured could be misleading due to interference from the high bromine concentration instead of true lead readings.

²⁴ Ecology Center, 2008. HealthyCar.org – The Consumer Guide to Toxic Chemicals in Cars: 2007 and 2008 Guides to Child Car Seats. Available at: <u>http://www.healthycar.org/carseat.using.php</u>

Testing for chlorine in car seats with the XRF device indicates the possible presence of polyvinyl chloride (PVC) plastic and was used by the Ecology Center as a surrogate for phthalate content. Phthalates are commonly used in PVC as plasticizers. Phthalates cannot be measured directly using an XRF device because this technology only measures individual elements. XRF results cannot be used to determine compliance with the CSPA phthalate standard because they do not provide quantifiable measures of phthalate content.

Fourteen out of 63 car seats and three out of 70 car seats contained chlorine, in the 2007 and 2008 testing, respectively. For the 2007 data, chlorine was measured in 9 shade components and 5 in trim materials. For the 2008 data, chlorine was measured in 2 car seat shades and in 1 sample of vinyl fabric. These results indicate that phthalates may be present in up to 17 (13%) of the car seats sampled over the two year period.

Cadmium was not detected in any of the 63 car seats testing in the 2007 sampling and in only 1 car seat in the 2008 sampling. For the one car seat containing cadmium, it was detected at a concentration above the 40 ppm standard in the seat component.

The Ecology Center data from 2007 and 2008 indicate that most surface components and materials of car seats would comply with the lead and cadmium standards. However, the Ecology Center testing did not include all parts of car seats such as internal materials and metals parts other than the front clip used for securing straps around a child's chest. The Ecology Center also does not provide data on the number of car seats with surface parts exceeding the CSPA standard for phthalates. The Ecology Center does indicate that many car seat components do not contain PVC, and are therefore less likely to contain phthalates.

Findings

- Based on information provided by the Juvenile Products Manufacturers Association, the CSPA standards are preempted for many car seats because they are multi-use products regulated by both the CPSC and NHTSA.
- Available testing data for surface components of car seats indicates that many car seats sold by major retailers in 2007 and 2008 would meet the CSPA standards for lead (90 ppm) and cadmium (40 ppm).
- Ecology and Health have not been able to obtain actual car seat testing data from manufacturers to evaluate which components of car seats would not comply or the actual levels of lead and cadmium in metal parts.
- Car seat manufacturers state that companies would have trouble meeting the CSPA lead and cadmium standard for metal parts used in car seats

- No car seat manufacturers stated that they would pull out of the Washington market because of the CSPA standards.
- Testing results indicate that most car seats do not contain surface components containing PVCs which are associated with the use of phthalates. Additionally, information reported from car seat manufacturers indicates that car seats will meet the CSPA phthalate standards

Recommendations

The Advisory Group considered the concern that implementation of the CSPA could result in reduced availability of safe car seats in Washington. Most of the concern was directed at the lead, cadmium and phthalate standards. The Advisory Group did not come to a conclusion regarding car seats but did recommend that the Department of Health continue to pursue information from manufacturers.

Ecology and DOH concluded that neither the safety nor the availability of car seats will be negatively impacted by this law. The agencies do recommend continued tracking of the implementation of the CPSIA. In addition, for those car seats regulated solely by the NHTSA, Ecology recommends that the issue be addressed as part of the CSPA rule making. Until the rule is adopted, Ecology should use its enforcement discretion and refrain from enforcing the standards in car seats regulated solely by the NHTSA.

Appendix 1

Comparison of the Washington Children's Safe Products Act and the Federal Consumer Product Safety Improvement Act

Washington State passed the Children's Safe Products Act (CSPA) in April, 2008. In August, 2008, President Bush signed the Consumer Product Safety Improvement Act (CPSIA). The federal statute preempts state standards for lead, cadmium, and phthalates in children's products. One goal of CPSIA was to have one statute for the entire country, replacing a patchwork of different state laws. California and Vermont have state laws that limit phthalates in children's products. California, Connecticut, Illinois, Maine, Michigan, Minnesota, and Vermont all have state laws on lead in certain children's products.

CPSIA requires manufacturers to certify that their products meet all applicable standards. This certification is based on individual tests or a testing program. Conformity assessment is through accredited third parties. The certificates must accompany the products, be provided to the distributor or retailer, and be provided to the Consumer Products Safety Commission (Commission) upon request. Electronic certificates are also an option.

While both CSPA and CPSIA cover lead, cadmium, and phthalates in children's products, they overlap in different ways for each chemical.

Lead

CPSIA mandates a lead limit of 600 ppm by February 10, 2009, 300 ppm by August 14, 2009, and 100 ppm by July 1, 2011 if feasible, as compared to the CSPA limit of 90 ppm by July 1, 2009. CPSIA also includes a lower limit of 90 ppm for most consumer paint as of August 14, 2009.

The CPSIA applies to children's products for children under 12, while the Washington law only specifies an age limit (under 12) for cosmetics and jewelry. The federal law directs the Commission to determine if it is feasible to include electronic components.

The federal law has two major exemptions that are not in the Washington law. The first is for inaccessible components. The second is that the federal Commission can decide by rule to exempt certain materials that don't result in lead absorption.

		Washington
Requirements	Federal CPSIA	CSPA
		Under 12 for cosmetics
Age	12 or younger	and jewelry
	600 ppm 2/10/09	
	300 ppm 1 yr, 8/14/09	
Limit	90 ppm for paint 8/14/09	90 ppm 7/1/09
	100 ppm (if feasible) 3 yrs,	
	8/14/11	

Table 2: Comparison of Lead Requirements for U.S. CPSIA and Washington CSPA

Phthalates

CPSIA has a phthalate limit of 1,000 ppm for each of the six regulated phthalates, which include BBP, DBP, DEHP, DINP, DIDP, and DNOP. The CSPA regulates the same six phthalates, but imposes a 1,000 ppm limit on total phthalate levels across all six.

The Washington law limits all six phthalates in all children's products. The federal law, however, limits three phthalates, DEHP, BBP and DBP, in children's toys and child care articles. A child care article is defined as a product that a child three and younger would use for sleeping, feeding, sucking or teething. The federal law only limits the other three phthalates, DINP, DIDP, and DNOP, in mouthable children's toys and child care articles.

Again, the Washington law only includes an age limit of under 12 for cosmetics and jewelry. The federal law regulates children's toys for age 12 and under and childcare articles for ages three and under.

The federal phthalate ban on DINP, DIDP, and DNOP in mouthable items is temporary. A panel will be convened to examine phthalate toxicity and report its findings. The panel will not begin until after 180 days and must finish within 18 months. The panel's report must be finished within 180 days. Within 180 days of receiving the report, the federal Commission will promulgate a final rule.

Table 3: Comparison of Phthalate Requirements for U.S. CPSIA and Washington CSPA

Requirement	Federal	Washington CSPA	
	mouthable	children's toy or	
	children's toy or	child care	children's products,
Products	child care article	article	as for lead
Date	180 days (2/10/09)		7/1/2009
Limit	1000 ppm each		1000 ppm total
DEHP	Х	Х	Х
BBP	Х	Х	Х
DBP	Х	Х	Х
DINP	Х		Х
DIDP	Х		Х
DNOP	Х		Х

Cadmium

For cadmium, the CPSIA incorporates the American Society for Testing and Materials (ASTM) standard F963-07, which mandates a limit of 75 ppm soluble cadmium in the surface coatings of toys, as compared to the CSPA's limit of 40 ppm total in children's products and components. By August, 2009, the Commission will evaluate these safety standards and promulgate a rule within a year of the completed assessment. The ASTM F963-07 standard applies to toys for children 14 and under and has exceptions for specific products.

Appendix 2

Sources of Information to Identify High Priority Chemicals

HPCs Sources - United States

Environmental Protection Agency

The U.S. Environmental Protection Agency (EPA) is the primary Federal Agency charged with protecting human health and the environment. As part of its mission, the EPA is responsible for enforcing a number of regulations and has established programs to work with businesses to address problems which impact their mission. Five EPA programs identify chemicals of concern appropriate for inclusion on the list of HPCs.

EPA PBT Program

EPA established a PBT program to reduce risks from, and exposures to, priority PBT chemicals. This program is intended to increase coordination among EPA national and regional programs with the aim of overcoming the remaining challenges in addressing these priority PBT pollutants.²⁵ As part this effort, EPA identified 12 high priority PBTs which require immediate action.²⁶ EPA established a chemical profile fact sheet and will develop an action plan for each of these PBTs.

EPA Toxics Release Inventory (TRI) Program

EPA implements the Emergency Planning and Community Right to Know Act (EPCRA) which requires businesses and other organizations to report chemical releases to the environment. As part of this regulation, EPA maintains the TRI database which summarizes releases reported to EPA under this regulation.²⁷ On October 29, 1999, EPA added reporting requirements for a list of Persistent, Bioaccumulative and Toxic (PBT) chemicals.²⁸ As stated in the notice, these PBTs were identified because PBTs

"...were found to be reasonably anticipated to cause serious or irreversible chronic human health effects or relatively low doses or ecotoxicity at relatively low concentrations, and thus are considered to have moderately high to high chronic toxicity or high ecotoxicity."

²⁵ More information on EPA's PBT program can be found at: <u>http://www.epa.gov/pbt/index.htm</u>, accessed 11/18/2008

²⁶ More information on EPA's Priority PBTs can be found at: <u>http://www.epa.gov/pbt/pubs/cheminfo.htm</u>, accessed 11/18/2008

²⁷ More information on EPA's EPCRA Program and TRI can be found at: http://www.epa.gov/triinter/triprogram/tri_program_fact_sheet.htm, accessed 11/18/2008

 ²⁸ Federal Register notice at: <u>http://www.epa.gov/EPA-WASTE/1999/October/Day-29/f28169.htm</u>, accessed 11/17/2008

In this process EPA identified four groups of chemicals such as dioxins and dioxin like compounds, mercury and lead compounds, and polycyclic aromatic hydrocarbons (PAHs) and 16 individual chemical species as PBTs. The Federal Register notice reported 64 specific Chemistry Abstract Services (CAS) numbers as PBTs.

Integrated Risk Information System

As EPA states on its website 'IRIS (Integrated Risk Information System) is a compilation of electronic reports on specific substances found in the environment and their potential to cause human health effects. IRIS was initially developed for EPA staff in response to a growing demand for consistent information on substances for use in risk assessments, decision-making and regulatory activities. The information in IRIS is intended for those without extensive training in toxicology, but with some knowledge of health sciences'.²⁹

IRIS currently contains information on 548 chemicals or groups of chemicals and IRIS can be searched to determine chemicals of concern due to specific toxicity criteria. For example, the 548 chemicals can be searched to determine which are known, likely and probable human carcinogens based upon EPA screening criteria.³⁰ 124 carcinogenic chemicals and 4 chemicals with non-cancerous impacts based upon their Oral Reference Dose (RfD) were identified.

National Waste Minimization Program

EPA established the National Waste Minimization Program which supports efforts to promote a more sustainable society, reduce the amounts of waste generated, and lower the toxicity and persistence of wastes that are generated.³¹ The National Waste Minimization Program established a list of priority chemicals which consists of 28 'Organic Chemicals and Chemical Compounds' and 3 'Metals and Metal Compounds'.³²

National Toxicology Program

The NTP is an interagency program managed by the U.S. Department of Health and Human Services (DHHS) whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The need for a program like the NTP arose because of increasing scientific, regulatory, and Congressional concerns about the human health effects of chemical agents in our environment.³³ The NTP has identified chemicals which pose a threat to human reproduction and which are known or suspected carcinogens.

 ²⁹ More information on EPA's IRIS can be found at: <u>http://cfpub.epa.gov/ncea/iris/index.cfm</u>, accessed 11/18/2008
 ³⁰ The search criteria and chemicals can be found on the IRIS site at:

http://www.epa.gov/ncea/iris/search_human.htm, accessed 11/18/2008 ³¹ More information on EPA's Waste Minimization Program can be found at:

http://www.epa.gov/osw/hazard/wastemin/index.htm, accessed 11/18/2008

³² More information on these chemicals can be found at: <u>http://www.epa.gov/osw/hazard/wastemin/priority.htm</u>, accessed 11/18/2008

³³ More information on the NTP and its work can be found at: <u>http://ntp.niehs.nih.gov/?objectid=720163C9-BDB7-</u> <u>CEBA-FE4B970B9E72BF54</u>, accessed 11/18/2008

NTP Center for the Evaluation of Risks to Human Reproduction

The NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) was established in 1998 to serve as an environmental health resource to the public and regulatory and health agencies. CERHR publishes monographs that assess evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse effects on reproduction and development and provide opinion on whether these substances are hazardous for humans.³⁴ Through this process, the CEHR has identified 40 chemicals of concern³⁵.

NTP Report on Carcinogens

The NTP also publishes a list of carcinogens in its Report on Carcinogens (RoC). The RoC is an informational scientific and public health document first ordered by Congress in 1978 that identifies and discusses agents, substances, mixtures, or exposure circumstances that may pose a hazard to human health by virtue of their carcinogenicity.³⁶ The RoC includes two categories of carcinogenic compounds:

- 1. Chemicals 'known to be human carcinogens'.
- 2. Chemicals 'reasonably anticipated to be human carcinogens'

The 11th RoC report identifies 56 Category A and 185 Category B carcinogens.

HPCs Sources - States

California's Proposition 65 Program

Proposition 65 (Prop 65), the Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted as a California ballot initiative in November 1986. Prop 65 was intended by its authors to protect California citizens and the State's drinking water sources from chemical chemicals known to cause cancer, birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals.³⁷

Each year, the Office of Environment Health Hazard Assessment section of the California EPA publishes an updated list of chemicals of concern. The list currently contains more than 700 unique chemicals that exhibit carcinogenic and/or reproductive toxicity.³⁸

³⁴ NTP CERHR found at: <u>http://cerhr.niehs.nih.gov/aboutCERHR/index.html</u>, accessed 11/17/2008

³⁵ Information on the CEHR list can be found at: <u>http://cerhr.niehs.nih.gov/chemicals/index.html</u>, access 11/18/2008

³⁶ NTP RoC found at: <u>http://ntp.niehs.nih.gov/?objectid=72016262-BDB7-CEBA-FA60E922B18C2540</u>, accessed 11/17/2008

³⁷ More information on Prop 65 can be found at: <u>http://www.oehha.org/prop65.html</u>, accessed 11/17/2008

³⁸ The Prop 65 List can be found at: <u>http://www.oehha.org/prop65/prop65_list/files/P65single091208.pdf</u>, access 11/18/2008

WA State PBT Program

In 2006, Ecology adopted regulations specific to PBTs (WAC 173-333). 27 PBTs are identified including 25 organic chemicals or chemical groups and two metals of concern. Washington's list includes 75 unique chemicals with individual CAS numbers.

HPCs Sources - International

International Agency for Research of Cancer

The International Agency for Research on Cancer (IARC) is part of the World Health Organization. IARC's mission is to coordinate and conduct research on the causes of human cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer control. The Agency is involved in both epidemiological and laboratory research and disseminates scientific information through publications, meetings, courses, and fellowships.³⁹ In addition, IARC publishes monographs which identify carcinogenic chemicals and separates them into four main groups:⁴⁰

Group 1: *Carcinogenic to humans*. (47 chemicals/chemical groups out of 105)
Group 2A: *Probably carcinogenic to humans*. (51 chemicals/chemical groups out of 66)
Group 2B: *Possibly carcinogenic to humans*. (221 chemicals/chemical groups out of 248)
Group 3: *Not classifiable as to its carcinogenicity to humans*. (515 chemicals)
Group 4: *Probably not carcinogenic to humans*. (1 chemical)

The chemicals in Groups 1 and 2 (both 2A and 2B) identified above were added to the HPC list.

European Union (EU) Substances of Very High Concern (SVHC) Program

The European Chemicals Agency (ECHA) prepares Annex XV dossiers for the identification of substances of very high concern which are carcinogenic, mutagenic or reproductive toxins (CMRs), PBTs or cause serious effects to human health or the environment of an equivalent level of concern as those above (e.g. endocrine disrupters).⁴¹ ECHA has only begun the process of identifying SVHCs and currently sources 16 on its website.

European Commission

The mission of the European Commission (EC) is to promote the general interest of the European Union. It presents proposals for European law, oversees implementation of Treaties

³⁹ More information on IARC can be found at: <u>http://www.iarc.fr/</u>, accessed 11/17/2008

⁴⁰ IARC Monographs found at: <u>http://monographs.iarc.fr/ENG/Classification/Listagentsalphorder.pdf</u> , accessed 11/17/2008

⁴¹More information on SVHCs can be found at:

http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp, accessed 11/17/2008

and European law and carries out common policies and managing funds.⁴² The EC conducts work on a wide range of environmental issues and has established several databases which address chemical specific issued undertaken by the EC to address chemical safety.

Endocrine Disruptor Program

On 20 December 1999, the European Commission adopted a Communication on a Community Strategy for Endocrine Disrupters – a range of substances suspected of interfering with the hormone systems of humans and wildlife. The strategy focuses on man-made substances, including chemicals and synthetic hormones, which may harm health and cause cancer, behavioral changes and reproductive abnormalities.⁴³ Endocrine disruptors were grouped into four major categories:

- Category 1: Evidence of endocrine disruption activity (194 chemicals)
- Category 2: Some evidence of biological activity related to endocrine disruption (125 chemicals)
- Category 3: No scientific evidence of endocrine disrupting activity
 - 3A: No data available on wildlife relevant and/or mammal relevant endocrine effects (23 chemicals)
 - 3B: Some data available but evidence is insufficient for identification (85 chemicals)
 - 3C: Data available indicating no scientific basis for inclusion in list (0 chemicalsdetails not provided)

The EC also provides an Access database which contains all of the chemicals reviewed and enables one to separate out the chemicals into the categories identified above⁴⁴. For the purposes of the Children's Safe Product Act, only Categories 1 and 2 were considered.

PBT Program

In June 2001, the EC initiated an interim strategy to identify and address PBT chemicals. The results of this work can be found in the internet databases, ESIS (European chemical Substances Information System) which identifies PBT (Persistent, Bioaccumulative, and Toxic) or vPvB (very Persistent and very Bioaccumulative) chemicals.⁴⁵ 127 potential PBT chemicals are listed in ESIS. Of these 127, 66 are identified as 'Not fulfilling PBT & vPvB criteria' and were eliminated from further consideration.

⁴² Governing Statement of the European Commission at:

http://ec.europa.eu/atwork/synthesis/doc/governance_statement_en.pdf, accessed 11/20.2008 ⁴³ More information on the EU Endocrine disruptors program can be found at:

http://ec.europa.eu/environment/endocrine/documents/sec 2007 1635 en.htm, accessed 11/17/2008 ⁴⁴ The database containing these endocrine disruptors can be found at:

http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list, accessed 11/18,2008 ⁴⁵ More information on EC PBTs can be found at: <u>http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt</u>, accessed 11/17/2008

Chemicals identified for Risk Assessment

The EC also maintains a website providing information to address the Existing Substances Regulation (ESR), which required a comprehensive framework for the evaluation and control of "existing substances". The ESR states that the EC, in consultation with Member States, will regularly draw up sources of priority substances which require immediate attention because of their potential effects to man or the environment.⁴⁶ 141 Compounds have been identified since this regulation passed in 1994.

Oslo-Paris Convention (OSPAR)

The OSPAR Commission, originally formed in 1972 to control dumping into the North Sea, is a consortium of 15 European Countries and the European Community whose mission is to protect the marine environment of the North-East Atlantic. OSPAR has expanded over the years to include land based and production sources of potential pollution to the North-East Atlantic. The 1992 OSPAR Convention is the current instrument guiding international cooperation to meet these objectives.⁴⁷

OSPAR identified chemicals of concern to the North-East Atlantic. The first of these is a list of 310 chemicals or chemical groups of possible concern which consists mainly of PBT chemicals with a few endocrine disruptors included.⁴⁸ OSPAR further identified a shorter list of 50 chemicals or chemical groups which require priority action.⁴⁹

Canadian Environmental Protection Act

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) is Canada's federal environmental legislation aimed at preventing pollution and protecting the environment and human health.⁵⁰ As part of this effort, the Canadian government evaluated all compounds imported or produced in Canada and prioritized them for various criteria. The results of these efforts are available on the web.⁵¹

For the purposes of the Children's Safe Product Act, only PBiT (persistent, bioaccumulative and inherently toxic) chemicals were considered for the HPC list.

http://www.ospar.org/content/content.asp?menu=00950304450000_000000_000000, accessed 11/18/2008 ⁴⁹ More information on OSPAR Chemicals for Priority Action can be found at:

⁴⁶ More information on ORATS can be found at: <u>http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=ora</u>, accessed 11/18/2008

⁴⁷ More information on OSPAR can be found at:

http://www.ospar.org/content/content.asp?menu=00010100000000 000000 000000, accessed 11/18/2008 ⁴⁸ More information on the OSPAR Chemicals of Possible Concern can be found at:

http://www.ospar.org/content/content.asp?menu=00940304440000_000000_000000, accessed 11/18.2008 ⁵⁰ For more information on CEPA see: http://www.ec.gc.ca/CEPARegistry/gene_info/, accessed 11/18/2008

⁵¹ CEPA found at: <u>http://www.ec.gc.ca/CEPARegistry/subs_list/dsl/dslsearch.cfm</u>, accessed 11/17/2008

HPCs Sources - Other

Grandjean & Landrigan Identification of Endocrine disruptors

Two well known toxicological researchers conducted a detailed evaluation of potential endocrine disruptors.⁵² Their identification of 201 industrial chemicals that have caused neurotoxic effects in man was based upon data from the Hazardous Substances Database of the U.S. National Library of Medicine, supplemented by fact sheets by the U.S. Agency for Toxic Substances and Disease Registry, and the Integrated Risk Information System (IRIS) of the U.S. EPA.

⁵² The Lancet at: <u>http://www.thelancet.com/lancet-about</u>, accessed 11/20/2008

Appendix 3

Sources of Information to Identify Potential Chemicals of High Concern for Children

Biomonitoring Data

The following two government sponsored studies on chemicals found in people were identified. These large scale studies provide information on chemicals which are found in human tissue, blood, and urine:

- The Center for Disease Control and Prevention (CDC) National Health and Nutrition Examination Study (NHANES)
- The Danish Birth Cohort

In 2005-2006, CDC interviewed approximately 7,000 U.S. residents and collected blood and urine samples from approximately 5,000 people.⁵³ The study is statistically controlled to distribute samples across all age and race groups which approximate the population distribution in the U.S. The CDC publishes many of its results in a yearly report and individual monographs of new analytical results as they come available. The NHANES study cited here is the *Third National Report on Human Exposure to Environmental Chemicals*⁵⁴ which includes data from 1999 to 2003 including data in the First and Second National Reports and articles published since the Third National Report was issued in 2005⁵⁵.

The Danish Birth Cohort is a program initiated in the Nordic Countries to determine the impact of numerous external stimuli upon the development of the children. Between 1997 and 2000, mother and child pairs were recruited into a long-term study to evaluate the impacts of early exposures upon long-term development. The aim was to recruit at least 100,000 pairs and as of 2000, 60,000 had been recruited.⁵⁶ A component of this research included obtaining blood samples from both mother and child and to have repeated contact every seven years as the child develops. Information from this study is just becoming available.⁵⁷ This study, while not

⁵³ CDC report at: <u>http://www.cdc.gov/nchs/data/nhanes/nhanes 05 06/general data release doc 05 06.pdf</u>, accessed 11/20/2008

⁵⁴ Report available at: <u>http://www.cdc.gov/exposurereport/pdf/thirdreport.pdf</u>, accessed 11/20/2008

 ⁵⁵ More recent monitoring results available at: <u>http://www.cdc.gov/exposurereport/</u>, accessed 11/20/2008
 ⁵⁶ From Olsen et al., *The Danish National Birth Cohort-its background, structure and aim*, Scan. J. Public Health

^{2001, 29, 300-307,} available at: <u>http://www.ssi.dk/graphics/html/bsmb/danishbirthcohort.pdf</u>, accessed 11/20/2008

⁵⁷ More information on the Danish National Birth Cohort is available at: <u>http://www.ssi.dk/sw9314.asp</u>, access 11/20/2008

specific to the American population, is still considered an appropriate source of information since the economies of Europe and the U.S are similar and therefore exposures are also likely to be similar.

In addition to these reports, studies published in peer reviewed, scientific journals were identified. These references do not represent an exhaustive compilation of the research conducted in these areas but are more of a snapshot of the types of studies that identify the characteristics of chemicals found in human tissue. The intent is to build the list of chemicals of high concern for children based on credible scientific studies. Ecology has identified the following publications as important for this effort. This list will be revised as new studies are published and more studies are reviewed.

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Indoor Air and Dust Data

Authoritative sources of information on chemicals found in indoor air and dust include:

- California Air Resources Board (CARB)
- German Environmental Survey (GerES)

The California Air Resources Board (CARB) is a part of the California Environmental Protection Agency and is the agency responsible for evaluating and protecting air quality for the residents of the state. CARB conducted research into a number of air pollution areas including indoor air in a report to the California Legislature in 2005.⁵⁸ The German Environmental Survey (GerES) is a nation-wide survey conducted to evaluate the exposure of the population to environmental contaminants. At least 5,000 people throughout Germany are included in the GerES⁵⁹ and chemicals in indoor air are one component of the survey.

In addition, the following publications were identified as sources of information about chemicals found in indoor air and dust. As indicated earlier, the references identified to date do not represent an exhaustive compilation of the research conducted in this area.

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Drinking Water Data

The U.S. EPA Drinking Water Program identified contaminants of concern in drinking water and established regulations to limit the concentrations of these chemicals.

Identification of published studies on chemicals found in drinking water is underway. The following reference list is provided as a snapshot of the types of studies conducted on toxic chemicals in drinking water.

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Consumer Product Data

The Danish Ministry of the Environment (Danish EPA) conducted studies on chemicals used in consumer products⁶⁰, many of which have been translated into English. For many of these studies, the Danish EPA went into the marketplace, purchased consumer products of interest and analyzed the products for chemicals of concern. They also conducted off-gassing or leaching

⁶⁰ More information on the Danish EPA program and related publications is available at: <u>http://www.mst.dk/English/Chemicals/Danish_initiatives/</u>, accessed 11/20/2008

studies on many of the products and included these results in their reports. These reports are the best source of information on chemicals in products the agencies have been able to identify.

To date, Ecology has identified 34 studies which document the presence of toxic chemicals in products including 13 which have focused specifically on products sold to or used by children.

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Danish Ministry of the Environment. Screening for health effects from chemical substances in textile colorants. Hansen, Ole Chr. 57. 2005. Survey of Chemical Substances in Consumer Products.

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The Ecology Center toy testing data

The Ecology Center toy testing program included toys and other children's products purchased from major chain stores including Target, Kmart, Toys R Us, Babies R Us, TJ Maxx, and Wal-Mart, as well as drug stores, dollar stores, on-line retailers and independent toy stores. Products were purchased from Ann Arbor and Ypsilanti, Michigan; Oakland, California; and Albany, New York. The selection of toys and other products for sampling was not random or designed to be representative of all products on the market. Information from this source will only be used if no other information is available.

Product categories tested included action figures & collectibles, activity gyms & play mats, arts & crafts supplies, backpacks, bath toys, crib toys, feeding products, bibs, dolls, costumes, infant books, soft & plush toys, pacifiers, rattles & teethers, outdoor toys & sporting goods, preschool & interactive toys, shoes, trains & construction toys, and vending machine toys.

The Ecology Center publishes toy testing results on their website, HealthyToys.org. The results are searchable by toy brand and toy type. Lead was the element detected the most of in the toys that were tested. Lead was detected in 20% (304) of the 1,528 products tested in 2008. Fifty-four of these products had lead concentrations above 600 ppm and seven products had lead concentrations above 10,000 (1% by weight). Six of the ten products with the highest lead levels were jewelry items.⁶¹ Children's jewelry was found to be five-times more likely than other products to contain lead above 600 ppm.

Toys were tested for other elements besides lead, and results indicate that these other elements were found less frequently in toys than lead at generally lower levels. Forty-five products tested in 2008 (2.9%), contained bromine at concentrations greater than 1,000 ppm. This indicates the use of brominated flame retardants in these products. Thirty products (1.9%) contained cadmium greater than 100 ppm, twenty-two products (1.4%) contained arsenic greater than 100 ppm, and fourteen products (1%) contained mercury greater than 100 ppm. Twenty-seven percent of non-jewelry products tested contained chlorine indicating the use of PVC plastic.

⁶¹ HealthyToys.org, Toy Rankings: sample high toys, <u>http://www.healthytoys.org/product.most.php</u>

Phthalates are commonly used in PVC plastic to make it soft and flexible. The Healthy Toy website reported that 62% of the toys tested had a Low concern ranking based on concentrations of elements that were found to be below existing toy standards or recommendations.

Appendix 4

Sources of Information to Support Prioritization of the List of Potential Chemicals of High Concern for Children

Exposure Assessment Guidance Documents

California EPA, 2004. Guidance for school site risk assessment pursuant to health and safety code Section 901(f): Guidance for assessing exposures and health risks at existing and proposed school sites. This report is a guidance document to assess exposures and health risks at existing and proposed school sites.

U.S. EPA, 2006. A framework for assessing health risks of environmental exposures to children. EPA/600/R-05/093F. The purpose of this report is to provide a framework for a more complete assessment of children's exposure to environmental agents and resulting health risks with the U.S. EPA risk assessment paradigm.

U.S. EPA, 2008. Child-Specific Exposure Factors Handbook. EPA/600/R-06/096F. This report provides updated information on various physiological and behavioral factors used in assessing children's exposure to environmental contaminants. These factors include: water ingestion; soil ingestion and non-dietary factors; inhalation rates; dermal factors including skin surface area and soil adherence factors; consumption of retail and home-grown foods; breast milk intake; body weight; activity pattern data; and consumer product use.

U.S. EPA, 2002. Summary report of the EPA/ACC technical workshop for the voluntary children's chemical evaluation program (VCCEP). Prepared by ERG, Inc.⁶² The report reflects information presented at a stakeholder meeting about methods for evaluating children's exposures.

The Netherlands National Institute for Public Health & the Environment (RIVM) and Food and Consumer Product Safety Authority, 2006. Chemicals in Toys: a general methodology for assessment of chemical safety of toys with a focus on elements. RIVM/SIR Revised Advisory Report 0010278A02, revised final version, Oct. 12, 2006⁶³. This report presents a risk-based methodology that can be used to assess the safety of exposure to chemicals in toys.

⁶² VCCEP Available at: <u>http://www.epa.gov/oppt/vccep/pubs/expsmrpt.pdf</u>

⁶³ RIVM Available at: <u>http://ec.europa.eu/enterprise/toys/documents/study_on_bioavailability.pdf</u>

References for Existing Prioritization Schemes

California EPA, 2001. Prioritization of toxic air contaminants under the children's environmental health protection act. Office of Environmental Health Hazard Assessment. This document describes the prioritization procedure used to develop an initial list of toxic air contaminants that may cause infants and children to be especially susceptible to illness per California Children's Environmental Health Protection Act.

Health Canada, 2003. Proposal for Priority Setting for Existing Substances on the Domestic Substances List under the Canadian Environmental Protection Act, 1999: Greatest Potential for Human Exposure, 2003.⁶⁴

*Health Canada, 2005. Proposed integrated framework for the health-related components of categorization of the domestic substances list under CEPA 1999. Release for Public Comment.*⁶⁵ This report outlines an integrated approach to categorization of substances on Canada's domestic substances list (DSL) with respect to both the "greatest potential for exposure" (GPE) and "inherently toxic" to humans (IThuman).

The Netherlands, 2004. Dutch Substances Policy in an International Perspective. This report includes the history of the Dutch chemical prioritization process and list of priority substances.⁶⁶

Zuurbier, M., et al., 2007. The environmental health of children: priorities in Europe. International Journal of Occupational Medicine and Environmental Health; 20(3):291-308.⁶⁷

Danish Ministry of the Environment (Danish EPA). The Danish EPA has conducted research on chemicals found in children's products and have included a health assessment based upon their results. As an example of their work, the Danish researchers evaluated baby products and reported their results in 'Survey, emission and health assessment of chemical substances in baby products'.⁶⁸

*U.S. EPA High Production Volume (HPV) Chemical Risk-based Prioritization*⁶⁹. EPA's riskbased prioritizations of high production volume (HPV) chemicals are screening-level documents that summarize basic hazard and exposure information and identify potential health risks to assist the EPA in deciding future actions. The prioritization documents are primarily based on hazard, use, and exposure data available to the Agency through the HPV Challenge Program and on EPA's examination of chemical use and exposure information.

⁶⁴ Available at: <u>http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/exposure/index-eng.php</u>

⁶⁵ Available at: http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/publi-comment/index-eng.php

⁶⁶ Report and related materials available at: <u>http://www.sharedspaces.nl/pagina.html?id=7386</u>

⁶⁷ Available at: <u>http://www.pinche.hvdgm.nl/resource/pdf/Zuurbier%20IJOMEH%202007.pdf</u>

⁶⁸ Available at: http://www.mst.dk/Udgivelser/Publications/2008/04/978-87-7052-717-0.htm?wbc purpose=basic&WBCMODE=presentationunpublished%23%23%23%23%23%23%23Knopurt

⁶⁹ Information about the EPA HPV Chemical Risk-based Prioritization process is available at: http://www.epa.gov/hpvis/aboutrbd.htm

Appendix 5

Summary of Laws Similar to the CSPA in Effect in Other States

California

In September 2008, California adopted two bills (AB 1879 and SB 509) designed to promote the goal of removing hazardous substances from consumer products and the environment. These bills are frequently referred to as California's 'Green Chemistry Laws.' AB 1879 enables the California Department of Toxic Substances Control (DTSC) to pursue regulations that establish a process to identify and prioritize chemicals of concern in consumer products. The law directs DTSC to adopt these regulations by January 2011. SB 509 establishes a process for making data on these chemicals and their toxicological properties available to the public through a web-based Toxics Information Clearinghouse, to be available by January 2012. Information to be collected on these chemicals will include a multimedia life cycle evaluation of the production, use, and disposal aspects of these chemicals.

This legislation provides an opportunity relative to the implementation of the Children's Safe Product Act. The DTSC will undergo a process to prioritize chemicals of concern in consumer products that will likely overlap significantly with the process under the CSPA.

The law directs DTSC to work with agencies in other states in the development of these chemical lists and life cycle analyses. Participating in this process could be advantageous for Washington's implementation of the CSPA. DTSC may identify problematic chemicals in children's products that would be appropriate supplements to the list of CHCCs, and could also provide valuable toxicological data on these chemicals. Furthermore, DTSC's process of life cycle analysis, if it is made public, could result in the identification of safer substitutes that will enhance the ability of Washington agencies to provide technical assistance to both small and large manufacturers in complying with the CSPA.

Connecticut

In June 2008, Connecticut enacted a children's product safety law, the Act Concerning Child Safety.⁷⁰ This law requires the state Commissioner of Consumer Protection, in consultation with the state Commissioners of Public Health and Environmental Protection to compile a list of toxic substances and the recommended maximum amount of each that may exist in children's products, along with a list of safer alternatives. The Commissioner of Consumer Protection is

⁷⁰ http://www.cga.ct.gov/2008/ACT/PA/2008PA-00106-R00HB-05650-PA.htm

the state Commissioners of Public Health and Environmental Protection to compile a list of toxic substances and the recommended maximum amount of each that may exist in children's products, along with a list of safer alternatives. The Commissioner of Consumer Protection is required to compile a list of children's products that contain banned hazardous substances and make it available on the department's website. The act also requires stores to post notices when Department of Consumer Protection designates an article as a banned hazardous substance. Failure to post the warning is considered an unfair trade practice. The act authorizes the Commissioner of Consumer Protection to take part in an interstate clearinghouse to classify chemicals according to the risks they pose.

Maine

Maine passed the Act to Protect Children's Health and the Environment from Toxic Chemicals in Toys and Children's Products in April 2008.⁷¹ The Maine law directs the state's Department of Environmental Protection (ME DEP) to identify priority chemicals of high concern. Manufacturers will be required to disclose how much of each priority chemical is in each children's product. The act authorizes ME DEP to require replacement of a priority chemical in children's products with a safer alternative whenever it determines that a safer alternative is available for a specified use. The act authorizes the state to participate in an interstate clearinghouse to share information and cooperate with other states to promote safer chemicals in consumer products. Ecology and Maine are sharing information and are using similar processes to identify chemicals that should be considered high priority.

⁷¹ http://www.besafenet.com/ppc/archives/purchasing/file031.pdf

Appendix 6

European Consumer Product Safety Laws

Directive 88/378 Toy Safety

EU Council Directive 88/378/EEC, Approximation of the Laws of the Member States Concerning the Safety of Toys, contains the harmonized regulations for toys sold in the EU. According to these regulations, toys must not contain dangerous chemicals within the meaning of the EU Council Directive 67/548/EEC and 88/379/EEC in amounts that are harmful to children⁷². This directive states that toys must not present a health hazard by ingestion, inhalation, skin or mucous membrane contact.

Toys are defined in the EU Toy Safety directive as "any product or material designed or clearly intended for use in play by children of less than 14 years of age". Annex I of Directive 88/378/EEC includes a list of articles that are not defined as toys. This list includes such products as sports equipment, air guns and air pistols, slings and catapults, darts with metallic points, toy steam engines, etc. Children's jewelry is also not considered a toy under Directive 88/378/EEC.

EN 71 Toy Safety Standards

The European Committee for Standardization (CEN) publishes a European Standard for the Safety of Toys (EN 71). This standard consists of nine parts covering mechanical and physical properties of toys, flammability, specification for the migration of certain elements (toxicity), specification for experimental sets for chemistry and related activities, chemical toys (sets) and other experimental sets, graphic symbols, organic chemicals, finger paints, swings and slides⁷³. The parts of this standard are listed below. Two parts of the standard pertaining to element migration standards (EN71, Part 3) and organic chemical standards (EN71 Part 9) are summarized below.

EN71 Part 3 (2000): Specification for Migration of Certain Elements

This standard specifies requirements and migration tests for eight elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium). The purpose of the standard is to address risks from these elements through ingestion exposure. Toys are

⁷² Van Engelen, et al., 2006. Chemicals in Toys, A General Methodology for Assessment of Chemical Safety of Toys with a Focus on Elements. RIVM/SIR Revised Advisory Report 0010278A02. Revised final version Oct. 12, 2006. Summary of EU toys standards are found in Appendices III and IV.

⁷³ British Toy & Hobby Association (BTHA), website. Available at: <u>http://www.btha.co.uk/education/template.php?id=162</u>

categorized according to the material they consist of, in order to determine the applicable test requirements for the migration of elements. This standard includes categories of toys with applicable test requirements for the migration of elements. The toy categories include coatings of paints, varnishes, lacquers, printing inks, polymers and similar coatings; polymeric and similar materials; paper and paper board; textiles (natural and synthetic); other materials including wood, leather and other porous substances; materials intended to leave a trace (e.g. graphite in pencils and liquid ink in pens); pliable modelling materials including clays; and paints, including finger paints, varnishes, lacquers, glazing powders and similar materials in solid or liquid form appearing as such in a toy.

EN71 Part 9 (2005): Organic Chemical Compounds - requirements

The standard addresses risks from certain organic chemicals through all possible contact routes. This part of EN 71 specifies requirements for the migration or content of certain hazardous organic chemical compounds from/in toys and toy materials by the following exposure routes: mouthing, ingestion, skin contact, eye contact and inhalation.⁷⁴ This includes the applicable migration or contact limits of organic chemical compounds depending on the type of toy and toy material. The standard prohibits or restricts either the presence or the release of 82 organic chemicals in toys, including colorants and primary aromatic amines, flame retardants, solvents, formaldehyde, monomers of plastics, plasticizers, and wood and other preservatives. The standards focus is on dangerous substances that should not be present or released from toys, based on risk assessment and risk management considerations. The requirements apply only to those toy materials and types of toy that are likely to present a risk to the health of children playing with toys.⁷⁵

New EU Toy Safety Standards

Recently the European Parliament adopted the European Commission's proposal to strengthen the EU rules on toy safety.⁷⁶ This proposal includes restrictions on substances that are carcinogenic, mutagenic or reproductive toxicants (CMRs) in accessible parts of toys. This ban applies to CMRs with a concentration above 0.1%.⁷⁷ The tolerable limit values have been reduced for some metals and those heavy metals which are particularly toxic, like lead or mercury, may no longer be intentionally used in toys. Allergenic fragrances are also restricted or are required to be labeled.

http://www.btha.co.uk/dynamic/documents/Recom_%20compliance_140606.doc ⁷⁵ EN 71-9 Solutions – Toy Safety, Reduce and Control Hazardous Substances in Toys. Available at: http://www.hardlines.sgs.com/en_719_toys_consumerproducts (accessed 01/16/09)

⁷⁴ British Toy & Hobby Association (BTHA), June, 2006. Guidance Document for Demonstrating Compliance to EN71 Parts 9, 10, 11 – Organic chemical compounds in toys. Available at:

⁷⁶ New EU Rules for Safe Toys for our children. EC press release. Available at: http://ec.europa.eu/enterprise/newsroom/cf/itemlongdetail.cfm?item_id=1996

⁷⁷ Commission of the European Communities, 2008. Proposal for a directive of the European Parliament and of the Council of the safety of toys. Available at:

http://ec.europa.eu/enterprise/toys/documents/com_2008_0009_en.pdf