

**Michigan Legislation to Assess Chemicals of Highest Concern in Children's Products**  
**Comments of the American Chemistry Council**  
**April 21, 2009**

The American Chemistry Council is pleased to offer comments on Michigan House Bills 4763-4769, the Children's Safe Products Act. ACC supports efforts to protect the children from harmful exposures to toxic chemicals. In addition, ACC supports many of the underlying concepts reflected in these bills, although we have a number of recommendations for improvements.

ACC represents the leading companies engaged in the business of chemistry. ACC members, including companies that are located in and do business in Michigan, apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. Many of these products – from life saving drugs to bike helmets, car seats and seat belts – help protect children.

ACC and its members are committed to improved environmental, health and safety performance, especially on fundamental issues like children's health. Through our industry's Responsible Care® program, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing, ACC and its members are committed to enhancing and improving the protection of health and the environment through chemistry.

ACC believes that recent efforts by industry and US EPA to develop toxicity exposure and health-related information about chemicals can be useful to the Michigan Department and the Department of Environmental Quality and the public. These efforts include:

- ACC and its members have worked to develop appropriate information on High Production Volume Chemicals (HPVs) – the approximately 3,000 chemicals that represent 95% of the volume of chemicals in U.S. commerce – and to make that information publicly available through the U.S. EPA's HPV Information System.
- We've worked with EPA in the Voluntary Children's Chemical Evaluation Program (VCCEP) to better understand how exposures to children can be best assessed.
- We've supported the National Institute of Child Health and Development's (NICHD) National Children's Study – a long term study of all the environmental factors, including physical and biological factors, possible chemical exposures, diet, and economic status among others that may influence children's health in the U.S.
- We've supported work to better understand Center for Disease Control and Prevention's (CDC) biomonitoring data that indicates the presence of chemicals in the human body. Important research must still be done to develop the scientific understanding to enable appropriate interpretation of these data and the possible implications for public health.

With more information about chemicals being made publicly available, EPA is making serious progress in its efforts to ensure the safety of existing chemicals through its Chemical Assessment and Management Program (ChAMP). This program is developing screening-level hazard, exposure, and risk characterizations for an estimated 6,750 chemicals produced or imported in quantities of 25,000 pounds or greater a year. Based on these assessments, EPA is prioritizing the chemicals to indicate whether additional data or control measures may be needed to address

potential hazards and risks. These prioritization efforts incorporate information about children's exposures to chemicals.

Earlier this month EPA Administrator Lisa Jackson asked that EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS) develop options to ramp up efforts to assess, prioritize, and take action on existing chemicals, with particular emphasis on protecting children. ACC urges Michigan legislators to review EPA's efforts under ChAMP because of its relevance to the Children's Safe Products Act under consideration. We direct you to EPA's new website on ChAMP at: <http://www.epa.gov/champ/> We also direct your attention to some attachments to this statement, detailing many of the public sources of data about chemicals.

### **Transparency in Information about Chemicals Is Good Public Policy**

ACC believes that legislation that improves transparency in the information available about chemicals used in children's products, including ingredient disclosure, is an appropriate policy objective. Such an approach can help assure that parents, chemical users, and the government have the appropriate information at hand to address concerns. ACC believes that legislation focusing on identifying and assessing priority chemicals of potential concern in children's products is appropriate.

This legislation's requirements -- for the state to identify the chemicals of highest concern in children's products; for manufacturers or distributors of children's products for sale in Michigan that contain those chemicals to provide information about the children's products and the chemicals contained in them; and for the State to post that information -- are generally sound. Prioritizing the State's actions on those few chemicals that may actually pose hazard and exposure risks to children will help assure that the State's limited resources are effectively and efficiently applied.

### **Priority Chemicals Should Be Identified Based on Both Hazard and Exposure Information**

To appropriately address priority chemicals, ACC believes that there should be a more specific focus on priority chemicals used in children's products on the basis of **both** hazard and exposure information. Neither hazard nor exposure information alone address whether a chemical poses any risk from its use in a product.

To a certain extent, this legislation attempts to integrate both hazard and exposure information through its proposed listing process. However, it simultaneously undercuts that approach. House Bill 4764's definition of "chemicals of concern" focuses on hazard information only -- by focusing on chemicals known to have certain hazard characteristics. But then the bill's definition of "chemicals of highest concern" focuses on use of those chemicals of concern in children's products and exposures to humans/environment deemed "significant" or relevant to Michigan children by the Department. In short, the bill's two definitions together address both hazard and exposure information together.

The bill's definition of "children's product" also undercuts an integrated approach to hazard and exposure by defining a children's product as any consumer product that merely "contains" a chemical of highest concern, that when used or disposed will likely result in a child or fetus being "exposed." This broad definition of "children's products" as any consumer product to

which a child or a fetus might be “exposed” is simply too broad. Secondly, because this definition focuses on “presence” of a chemical in a consumer product as a surrogate for “exposure” -- without any notion of whether or to what extent there may be an actual exposure that causes harm – the legislation undoes the notion of significant exposure included in the definition of “chemical of highest concern”.

The mere presence of a chemical in a product, in and of itself, does not indicate a potential concern for health or environmental impacts. Assume for the moment that a chemical found in the environment is also used to manufacture car seats for babies. The use of that chemical may be critical to confer the very safety qualities sought in a car seat, and yet without some evidence of an exposure risk, the chemical could be designated as a chemical of highest concern under the definition of “children’s product”. The definition of “children’s product” disregards the well-accepted toxicological principle that “dose makes the poison” and effectively imposes an absolute zero threshold for purposes of identifying chemicals of highest concern in children’s or consumer products. Any chemical that is “present” in any consumer product has a potential for “exposure.” But a chemical shouldn’t be of highest concern unless its presence in a product and its use lead to an exposure of significance. Mere presence does not mean there are harmful exposures. ACC urges the Michigan House to redress this inconsistency in its definitions of because it undercuts the legislation’s attempt to appropriately focus on priority chemicals on the basis of both hazard and exposure information.

In addition, the definition of “chemical of concern” allows the state to use “preliminary evidence” where “credible scientific data” do not exist. This is not a science based approach to identifying chemicals of concern, and raises significant uncertainties about the quality of the data that might be considered “preliminary evidence.”

### **Information Gathering Should Be More Useful and Not Overly Burdensome**

While HB 4764 establishes a requirement for the government to list chemicals of concern and highest concern in children’s products sold in Michigan and then imposes an information gathering process (HB 4766) about these chemicals on consumer product manufacturers, the information requested of manufacturers is more burdensome than useful to either the State or manufacturers/distributors of children’s products.

Manufacturers are asked to provide information about the number of “units” of the product sold in Michigan and on the “amount” of each chemical of highest concern in each “unit” of the children’s product. In general, these are burdensome requirements, as they imply a requirement to test for the presence of the chemical without regard to a threshold, and without regard to whether there is any risk of exposure. It is not clear what purpose this information will serve, or whether other information might be more useful given the policy objective. For example, information about expected exposure from the listed products would appear to be more useful in understanding the potential risks than simplistic information about the mere presence of a substance in a product.

### **Authority for Safer Alternatives Is Open-ended**

HB 4767 provides authority to the State to participate in interstate clearinghouses to promote “safer alternatives” in consumer products. ACC believes that any such “clearinghouse” should

be sponsored by government(s), should include stringent criteria for the quality of data available from such a clearinghouse, and should provide a means for reviewing the potential comparative risks of “alternatives”, their costs, or information about the chemicals of highest concern.

HB 4764 defines a “safer alternative” purely on the basis of its ability to reduce the potential for harm to human health or the environment or as an alternative that has “not been shown” to pose the same or greater potential for harm as the chemical of concern. This definition fails to consider other key product development issues such as the risks of the alternative, and the implications for quality, feasibility, and cost.

The definition also appears to create a much lower standard for “alternatives” to meet than what chemical products must meet in real world consumer product development. Under the legislation, an alternative can be identified as “safer” if it has “not been shown” to have the same or greater potential for harm. This implies that a relatively unstudied chemical could be tagged as safer simply because it has not been evaluated as thoroughly as the chemical of concern. Including this definition in the legislation with an open-ended, unclear authority to participate in other unidentified interstate clearinghouses on promotion of “safer alternatives” is problematic.

Last year, California Governor Arnold Schwarzenegger signed into law A.B. 1879, legislation that granted the California Department of Toxic Substances Control (DTSC) broad regulatory authority over chemicals in consumer products. Among other things, the California legislation establishes a process to evaluate the availability of alternatives and their potential risks, relying on life cycle assessment tools that evaluate, among other things,

- Product function or performance
- Materials and resource consumption
- Water quality and conservation
- Air emissions
- Production, in-use, and transportation energy inputs
- Energy efficiency and greenhouse gas emissions
- Public health impacts, including potential impacts to sensitive subpopulations, including infants and children
- Environmental and economic impacts

The California legislation is instructive in that it establishes a framework by which the State is to address chemical risks in consumer products (including risks in children’s products). Michigan legislators may want to consider whether some of these elements would be useful to include in the definition of safer alternatives in order to ensure that any future participation by the state in such efforts is well grounded in scientific life cycle assessment.

### **Conclusion**

Any program that aims to enhance the safety of children’s products that contain chemicals should be built upon the following principles:

- Apply and leverage existing scientific information about chemical uses in children’s products. (See EPA’s ChAMP and ACC’s attachment to this statement).

- Rigorously evaluate the potential risks from exposures to chemical uses of concern in children's products.
- Identify chemicals of highest concern based on uses that have the greatest potential for exposures to children.
- Provide a transparent process that affords all stakeholders, including affected businesses, the opportunity for comment and input on the assessment of chemical uses in children's products, including input on the scientific basis for the listing, the potential alternatives to certain chemical uses, and the practical impacts of the listing process itself.

## **ATTACHMENT**

### **SOURCES OF PUBLIC INFORMATION ON CHEMICALS**

There is a common misconception that there isn't a lot of information available on chemicals and their effects on people and the environment. But an abundance of information on chemicals is easily available to the public, researchers, government regulators, and industry via the internet. Learn more at the following sources.

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**National Library of Medicine.** For nearly 40 years, the National Library of Medicine's (NLM) Toxicology and Environmental Health Information Program (TEHIP) has been a significant leader in organizing and providing public access to an extensive storehouse of toxicological information through its online databases. With the advent of the Internet, TEHIP has expanded its role to also serve as a pre-eminent portal to toxicological information worldwide. Its primary databases reside within the web-based TOXNET system, and include the scientifically peer-reviewed Hazardous Substances Data Bank (HSDB), the U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS) and Toxics Release Inventory, the National Cancer Institute's Chemical Carcinogenesis Research Information System (CCRIS) and the TOXLINE file of over 3 million bibliographic references.

TEHIP's ChemIDplus is an extensive chemical dictionary that extends beyond simple nomenclature to offer displays of molecular structures and links from particular chemicals to other databases containing more information. Specialty files in occupational safety and health, and household products have recently been added to TEHIP's suite of resources. Additional databases in risk assessment, drugs, toxicology education, and global resources, are under development. "Special Topics" pages lead users to structured summaries and links in areas such as arsenic, chemical warfare agents, biological warfare, and West Nile Virus. A database on alternatives to the use of live animals, a three-module toxicology tutor, and a glossary of terms in toxicology are among TEHIP's other information aids, as well an increasing commitment to serving consumers, as witnessed by the animated ToxTown program. Outside the sphere of TEHIP, NLM offers additional databases, such as PubMed, of significant value to toxicology researchers.

The database is available at the National Library of Medicine's "Environmental Health & Toxicology" web page at <http://sis.nlm.nih.gov/enviro.html>. A 100 page user manual is available online called "TOXNET and Beyond: Using the National Library of Medicine's Environmental Health and Toxicology Portal" at <http://sis.nlm.nih.gov/enviro/toxnetmanual112008.pdf>.

**ATSDR.** The Agency for Toxic Substances and Disease Registry (ATSDR) produces *Toxicological Profiles* for hazardous substances found on the National Priorities List (NPL) of

contaminated sites. ATSDR also prepares toxicological profiles for the Department of Defense (DOD) and the Department of Energy (DOE) on substances related to federal sites. The *Toxicological Profiles* summarize in detail existing hazard and exposure information on chemicals, and are written for technical audiences.

The ATSDR ToxFAQs™ is a series of summaries about hazardous substances for general audiences. Information for this series is excerpted from the ATSDR *Toxicological Profiles* and Public Health Statements. Each fact sheet serves as a quick and easy to understand guide. Answers are provided to the most frequently asked questions (FAQs) about exposure to hazardous substances found around hazardous waste sites and the effects of exposure on human health.

- **ATSDR, Toxicological Profiles and ToxFAQs:** <http://www.atsdr.cdc.gov>

**High Production Volume Chemicals.** Under the "HPV Challenge" program American Chemistry Council members are making screening information and test data publicly available on high production volume (HPV) chemicals. HPV chemicals represent more than 95 percent of the U.S. market for commercial chemicals by volume. Information provided includes 17 endpoints internationally agreed as sufficient to initially assess chemical hazards including physical/chemical properties, environmental fate, ecotoxicity, and hazards to human health. This program has already made more data publicly available - and faster - than any chemical regulatory program in history. For more information and to view the data, visit the HPV Challenge web sites at:

- **US HPV Chemical Challenge Program:** <http://www.epa.gov/hpv/pubs/hpvrstp.htm>
- **Environmental Protection Agency (EPA)'s HPV Information System:** <http://www.epa.gov/hpvis/index.html>

EPA is in the process of sorting and prioritizing the data in the High Production Volume Information System (HPVIS) through use of an algorithm established by a federal advisory committee (the National Pollution Prevention and Toxics Advisory Committee - NPPTAC). The results of EPA's prioritization, any decisions on further data or risk management needs, and assessment of those chemicals will be publicly available.

In 2007, the EPA began development and post interim screening-level hazard characterizations for chemicals that were part of the HPV Challenge Program. In 2008, EPA updated the interim screening-level hazard characterizations and combined them with use and exposure data under the 2006 Inventory Update Reporting (IUR) Rule to develop and post Risk-Based Prioritizations (RBPs). The RBPs identify potential risks, note

scientific issues and uncertainties, and indicate the initial priority being assigned by the Agency for potential future appropriate action. In 2008, as part of the Agency's commitment under the Chemical Assessment and Management Program (ChAMP), EPA began developing initial evaluations of moderate production volume (MPV) chemicals – those chemicals with production between 25,000 pounds and one million pounds per year.

ACC has also produced and posted a short video with helpful hints on how to search for chemical information. See

[http://www.americanchemistry.com/s\\_acc/sec\\_policyissues.asp?CID=316&DID=1142](http://www.americanchemistry.com/s_acc/sec_policyissues.asp?CID=316&DID=1142).

- HPV Chemical Hazard Characterizations: <http://www.epa.gov/hpvis/abouthc.htm>
- MPV Chemical Hazard-Based Prioritizations: <http://www.epa.gov/champ/pubs/abouthbp.htm>
- Risk-based prioritizations: [http://iaspub.epa.gov/oppt/hpv/hpv\\_hc\\_characterization.get\\_report?doctype=1](http://iaspub.epa.gov/oppt/hpv/hpv_hc_characterization.get_report?doctype=1)
- HPV Screening Process: <http://www.epa.gov/oppt/npptac/pubs/recommendations.htm>

**VCCEP.** Under the Voluntary Children's Chemical Evaluation Program (VCCEP), EPA evaluates both hazard and exposure information submitted by companies which have volunteered to in this pilot program to determine potential effects on children's health. This information is publicly available at:

- VCCEP: <http://www.epa.gov/chemrtk/vccep/index.htm>

**TSCATS.** The Toxic Substance Control Act Test Submission database, TSCATS, is a central system for the collection, maintenance, and dissemination of information on unpublished technical reports submitted by industry to EPA under TSCA. Studies on over 8,000 chemicals are categorized into three broad subject areas (health effects, environmental effects, and environmental fate). Searches can be conducted using these subject areas as well as indexing terms.

- TSCATS: [http://www.syrres.com/eSc/tscats\\_info.htm](http://www.syrres.com/eSc/tscats_info.htm)

**Integrated Risk Information System.** EPA and its Office of Research and Development maintain an electronic database called the Integrated Risk Information System (IRIS) and it contains descriptive and quantitative information on human health effects that may result from exposure to various chemicals in the environment. According to EPA's website, IRIS was initially developed for EPA staff in response to a growing demand for consistent information on chemical substances for use in risk assessments, decision-making and regulatory activities. Information in IRIS is intended for those without extensive training in toxicology, but with some knowledge of health sciences. The heart of the IRIS system is its collection of computer files covering individual chemicals.

- **To learn more about IRIS and to view the list of IRIS substances visit:**  
<http://www.epa.gov/iris/>

**ESIS.** The European Chemical Substance Information System (ESIS) is an electronic system that provides information on both new and existing substances in the EU. It includes proposed classification and labeling for 3,300 chemicals, information and data for roughly 2,500 EU HPV chemicals and final risk assessment reports for chemicals with completed assessments. ESIS also allows users to download the data on chemicals submitted in IUCLID.

- **ESIS can be found at:** <http://ecb.jrc.it/ESIS/>

The European Union REACH program is expected to result in the availability of hazard data on all chemicals in the European market, as well as use-specific chemical risk assessments for chemical on the European market above a specific threshold. Data will be publicly available, and fully searchable, formatted in software known as IUCLID.

**Organization for Economic Cooperation and Development.** The International Council of Chemical Associations has committed to submit data and assessments for 1,000 global HPV chemicals to the 30 developed nations of the OECD for government assessment. OECD assessments are published as soon as they are completed on the OECD website. The data included in those assessments are also available, via the United Nations Environment Program (UNEP).

- **OECD HPV Database:** <http://cs3-hq.oecd.org/scripts/hpv/>

- **UNEP HPV Datasets:** <http://www.chem.unep.ch/irptc/sids/OECDSEDS/sidspub.html>

The EXICHEM database is a pointer system on current, planned and completed activities on existing chemicals in OECD member countries and other relevant bodies. It was created to provide information for the OECD member countries on "who is doing what with which chemicals", (e.g. information gathering, testing, evaluation), in order to assist countries that are identifying opportunities for co-operation.

- **EXICHEM is found at:** <http://webdomino1.oecd.org/ehs/exichem.nsf>

**IPCS.** The International Program on Chemical Safety (IPCS - a joint program of UNEP, ILO and WHO) developed INCHEM - a freely available collection of internationally peer-reviewed documents about chemicals and chemical safety. It was initiated in 2003 in response to priorities established by the Intergovernmental Forum on Chemical Safety (IFCS) and provides convenient worldwide full-text electronic access to chemical safety-related documents provided by intergovernmental organizations. All documents referenced by INCHEM contain hazard information and the site can be queried by keywords and free text. INCHEM contains Environmental Health Criteria documents, and cancer assessments by the International Agency for Research on Cancer.

The International Chemical Safety Cards (ICSC) found on the IPCS site summarizes essential information on chemical substances; developed cooperatively by the IPCS and the Commission of the European Union (EC). The International Chemical Safety Cards summarize essential health and safety information on chemical substances in a clear way, and are not only intended to be used at the "shop floor" level by workers, but also by other interested parties in factories, agriculture, construction and other places of work.

Also on the IPCS site are Environmental Health Criteria (EHC) documents. These documents provide critical reviews of the effects of chemicals on human health and the environment. They include technical information on sources of exposure, environmental transport, health effects, and kinetics/metabolism in laboratory animals. There are more than 200 EHC documents posted.

The IPCS site also provides access to Concise International Chemical Assessment Documents (CICADs), which characterize hazard and dose-response to exposures of chemicals. They summarize the information considered critical for risk characterization.

- IPCS INCHEM: <http://www.inchem.org/>
- INCHEM ICSC: <http://www.inchem.org/pages/icsc.html>
- A list of chemicals with EHC documents can be found at [http://www.who.int/ipcs/publications/ehc/ehc\\_alphabetical/en/index.html](http://www.who.int/ipcs/publications/ehc/ehc_alphabetical/en/index.html)
- The CICADs are posted at [http://www.who.int/ipcs/publications/ehc/ehc\\_alphabetical/en/index.html](http://www.who.int/ipcs/publications/ehc/ehc_alphabetical/en/index.html)

**EDF Scorecard.** The Environmental Defense Fund created Scorecard.org, which provides information on more than 11,200 chemicals, including chemicals used in large amounts in the United States and the chemicals regulated under major environmental laws. You can search for information by typing in the chemical's name (or any common synonym) or the chemical's standard identification number (Chemical Abstracts Service or CAS registry number).

- <http://www.scorecard.org/chemical-profiles/>

