



August 13, 2010

John R. Williams  
Washington State Department of Ecology  
W2R HQ  
PO Box 47775  
Olympia, WA 98540-7775

**Re: Comments on Preliminary Draft Reporting Rule for Children’s Safe Products Act of 2008**

Dear Director Williams:

Based in Washington, D.C., the Grocery Manufacturers Association is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders.

In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools and information they need to achieve a healthy diet and an active lifestyle.

The food, beverage and consumer packaged goods industry in the United States generates sales of \$2.1 trillion annually, employs 14 million workers and contributes \$1 trillion in added value to the economy every year.

GMA supports the concepts behind the nationwide Green Chemistry Initiatives (GCI), and advocates for state regulations are workable, practical, and consistent and ensure protection of public health and the environment. GMA continues to strive for development of policies that stimulate Green Chemistry innovation and the promotion of greener technologies. GMA has been monitoring the progress of CSPA development the Department’s effort to establish rules that protect the health of children and are that workable and practical. GMA appreciates the opportunity to provide feedback on Washington Department of Ecology’s Preliminary Draft Reporting Rule released Thursday, July 29, implementing Washington’s Children’s Safe Products Act of 2008.

GMA respectfully submits this letter expressing concerns with key issues in the chemical prioritization and selection process used in developing the CHCC list, the resultant listing of a number of specific chemicals and the unworkable approach to trigger levels for reporting.

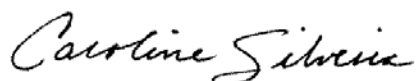
GMA believes that any state agency embarking on the green chemistry initiative should focus its limited resources on the chemicals and exposures of greatest impact to human health. This can be accomplished by assuring that key criteria are established to identify, prioritize, assess, and manage high priority chemicals. A prioritization of chemicals must be done in a way that focuses on those substances that are of greatest, known concern to human health and the environment. Generally, we support:

- Risk-based prioritization to identify chemicals of highest concern through exposure, use, and hazard data relevant to the U.S. population; and
- A “weight-of-evidence” approach to chemicals prioritization that evaluates authoritative information on hazard traits, and considers the most severe hazards first.

GMA specific comments below discuss these key issues and specific recommendations in the context of the mandates of this statute and provide specific input on the data sources and approach used in populating the Chemical of High Concern to Children (CHCC) list.

GMA is committed to assisting the Department in developing a credible and workable Green Chemistry program that will not only achieve the Green Chemistry Initiative’s objectives, but also be a model for the U.S. If you have any questions or comments, please feel free to contact us. We look forward to our continued work together on this important public policy initiative.

Sincerely,



Caroline Silveira  
Director, State Affairs  
Grocery Manufacturers Association  
1215 K Street, Suite 1500  
Sacramento, CA 95814

## Attachment 1—Detailed Comments

### Prioritization Criteria and Sources

Washington's Department of Ecology has taken an in depth approach to scanning the globe for hazard and exposure information and a series of steps in coming to decisions about primary versus secondary sources to determine priorities and a phase 2 ranking approach to select chemicals for reporting. In some areas, the choices seem to be reasonable; however, there remain significant concerns with the process employed and GMA requests that chemical selection be updated to reflect the following changes and suggestions.

#### HAZARD SOURCES

GMA concerns with sources used during priority setting are as follows:

- **"Known" Hazards.** The legislation focuses attention on high priority chemicals that "...on the basis of credible scientific evidence as **known** to do one or more of the following..."<sup>1</sup>. In toxicology, "known" is the most stringent standard for knowledge about a chemical's toxicological properties, and indicates that the weight of the evidence evaluation of the available data and information supports the determination. "Known" means that there has been an expert judgment made based on appropriate, quality scientific information. It does not mean that the evidence *suggested*, or that a hazard is *suspected, potential, or possible*. A known carcinogen, a known reproductive toxicant. The known criterion should be used to appropriately narrow the focus to the very highest hazard priorities, however, DoE did not adhere to this "known" hazard criterion in its chemical selections.
- **Hazard Severity.** There does not seem to be a transparent set of criteria for consideration of "severity"—e.g., that chemicals which have multiple hazards or have been reviewed and classified by more than one authority should receive higher priority. Nor is there a consideration of the severity of the type of toxicity—carcinogens and reproductive toxicants whose effects are seen chronic, repeated exposures at relatively low doses would clearly be more severe than chemicals having one-time (acute) or subchronic effects that are seen at relatively high doses or are reversible.
- **Inappropriate Hazard Information Sources.** Washington should only be selecting chemicals from source information that is authoritative in nature. Authoritative would be a government agency or formalized scientific organization that: (1) characterizes chemicals pursuant to an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments; (2) is widely perceived to be objective, scientifically based, and does not engage in advocacy; (3) bases its characterization of chemicals on a weight-of-evidence approach; (4) publishes its characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications. The Department of Ecology has drawn from a very

---

<sup>1</sup> "'High priority chemical' means a chemical identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative by the department on the basis of credible scientific evidence as **known** to do one or more of the following..."  
(<http://apps.leg.wa.gov/RCW/default.aspx?cite=70.240.010>)

large and heterogeneous global set of source lists. Many chemical selections are inappropriate either because the source was not authoritative in nature or because chemicals were selected from sections of authoritative lists that go beyond the “known” standard in the statute. Specific concerns:

- Proposition 65 developmental/reproductive. Because there are different routes by which a chemical may be listed under Prop 65, the basis for the listing – and not just that fact that a chemical is listed - must be considered. Prop 65 is an authoritative source for those chemicals that are listed per the recommendation of the CA Developmental and Reproductive Toxicant Identification Committee (DARTIC). Prop 65 may be an authoritative source for chemicals that are listed based on certain “authoritative bodies,” e.g., NTP CERHR, however, certain other bodies considered “authoritative” for purposes of Prop 65 listing purposes are inappropriate for consideration by the Department under the CSPA (e.g., some occupational hazards listed in the CA Labor Code).
- NTP CERHR finding. This is an authoritative source, however, unlike the approach used for every other source, the Department did not use the actual CERHR classifications in developing the CSPA chemical determinations, but rather an alternative approach. To be consistent and transparent, CERHR’s classifications should be applied directly, as are every other ranking from every other source. The logical approach, following rankings used from other sources would be: Worst—Serious Concern; Severe—Concern; Bad—Some concern.
- EU Existing Substances (Reproductive/Developmental). This is an authoritative source, however some chemicals selected ranked Category 1A and 2 were designated *Presumed* and *Suspected* by the EU (not “known”). The analysis also does not seem to acknowledge EU classification Category changes made in January 2010 (Category 1A, 1B and 2, instead of the previous Category 1, 2, 3).
- Japan GHS Reproductive/Developmental. This is an authoritative source, however some chemicals selected ranked Category 1B were in fact designated *Presumed* by Japan GHS (not “known”).
- REPROTEXT. This is not a public database, and is not searchable to confirm the information included or the criteria used. For transparency purposes, it should not be a source for any decisions in CSPA, a program that itself is aimed at increasing transparency of chemicals contained in consumer products.
- LOAEL or RTECS. This category is puzzling and not well explained in the Phase 2 report. It appears from the hyperlinks that it is aware of information in ATSDR and/or from Canada’s Occupational Health and Safety databases, but was the information from ATSDR or RTECS used at all in making selection decisions? The only ranking for diethyl phthalate in the Dev. & Repro. category was an indication that the chemical met the Worst ranking for oral, however the Final Dev. & Repro Determination in the p2 score sheets was “Phase 3”, suggesting that this factor is not being used for Determinations. Like REPROTEXT, Canada’s database is not open to the general public or searchable to confirm the information included or the criteria used, so it should not be a source of decisions in a program that is about transparency. The other major concern is the set of values indicated in the Worst/Severe/Bad rankings. What is this source of these? Are they supposed to be the values for acute toxicity from the GHS system? Values for repeat dose toxicity from GHS? Without clear and

transparent decision logic and data sources backing up this part of the determination process, this section of the evaluation should be removed.

- EU Endocrine Disruptors. This is not a reliable source for CSPA and should not be used in any respect. This list was developed in 1999 by a consultant, BKH. It never had any kind of deliberative scientific review or decision-making by EU Authorities and no input by stakeholders. It does not represent any level of scientific consensus. In fact, a review by the EU's Science Advisors (CSTEE) did "not find the source material, methodology and selection criteria used to be scientifically adequate" and concluded "that there are important shortcomings in the present approach". (EU Scientific Committee on Toxicity, Ecotoxicity and the Environment, Opinion on BKH Consulting Engineers Report [http://ec.europa.eu/health/ph\\_risk/committees/sct/docshhtml/sct\\_out73\\_en.pri nt.htm](http://ec.europa.eu/health/ph_risk/committees/sct/docshhtml/sct_out73_en.pri nt.htm)). There have been no changes or updates to the BKH work since the CSTEE review, nor any EU regulatory activity based on it. It has no place as a source in CSPA.
- IARC. This is an authoritative source, however some chemicals selected are from Group 2a Carcinogens (not "known").
- National Toxicology's Program (NTP) Carcinogens. This is an authoritative source, however some chemicals were selected that NTP had classified *Anticipated* (not "known").
- EPA IRIS. This is an authoritative source, however some chemicals selected ranked Category B1, B2 or Likely (not "known").
- EU Carcinogens. This is an authoritative source, however some chemicals selected ranked Category 1A and 2 were classified as *Presumed* or *Suspected* by the EU (not "known"). The analysis also does not seem to acknowledge EU classification Category changes made in January 2010 (Category 1A, 1B and 2, instead of the previous Category 1, 2, 3).
- Japan GHS Carcinogens. This is an authoritative source, however some chemicals selected ranked Category 1B are categorized by Japan GHS as *Presumed* (not "known").
- Proposition 65 Carcinogens. This is in part an authoritative source. Because there are different routes by which a chemical may be listed under Prop 65, the basis for the listing – and not just that fact that a chemical is listed - must be considered. Prop 65 is an authoritative source for those chemicals that are listed per the recommendation of the CA Carcinogen Identification Committee, however, certain other bodies considered "authoritative" for purposes of Prop 65 listing purposes are inappropriate for consideration by WA under CSPA (e.g., some occupational hazards listed in the CA Labor Code).

## EXPOSURE SOURCES

- A major concern in this part of the prioritization is the dependence on non-US information (Danish, Dutch, EU) about product uses and exposures and the weight assigned to those sources versus US EPA, FDA and NLM databases. The EU Risk Assessment work is a very old source (e.g. 15+ years). It should not be used for CSPA except in the case of chemicals where regulatory actions were taken to reduce children's exposures following completion of the risk assessment. In addition, the use of

an environmental advocacy group's database (EWG) has no place in a deliberative state scientific process for identifying priorities.

- EPA's Voluntary Children's Chemical Evaluation Program. This was a list developed by EPA about 10 years ago and led to the development of risk assessments for each of the chemicals. The development of the list did not include any direct information on Children's exposure and should be excluded from this chemical selection process, unless the VCCEP chemical assessments themselves document exposures of concern to Children.

### **APPROPRIATE SOURCES FOR IDENTIFYING KNOWN HAZARDS**

The following offers a recommendation for WA DoE on clear criteria and on a set of global Authoritative Body source lists to support identification of chemicals for CSPA. It would be appropriate for Washington to first focus on "known" Reproductive, Developmental toxicants and Carcinogens for the initial of reporting.

#### Criteria

"Chemicals known to cause cancer in humans" means chemicals that have been classified in (i) the International Agency for Research on Cancer ("IARC") category 1 or (ii) an equivalent category in a similar classification system promulgated by another authoritative body such as US EPA, California Proposition 65 (subject to the caveat explained above), the National Toxicology Program Report on Carcinogens, or the European Union. "Chemicals known to cause reproductive harm" means chemicals that have been classified as known reproductive or developmental toxicants by an authoritative body such as US EPA, California Proposition 65 (subject to the caveat explained above), the National Toxicology Program Center for Evaluation of Risks to Human Reproduction (CERHR), or the European Union.

#### Relevant Sources

- EPA Carcinogens. This has been collected since 1986 and the main challenge is that the ranking terminology has changed 4 or 5 times, most recently in 2005. Chemicals included should be those classified as Known or Category A. (<http://www.epa.gov/opp00001/health/cancerfs.htm>)
- NTP Report on Carcinogens. Chemicals included should be those classified as Known to Cause Cancer in Humans (<http://ntp.niehs.nih.gov/?objectid=72016262-BDB7-CEBA-FA60E922B18C2540>)
- Prop 65. Chemicals included should be Carcinogens and Repro/Developmental toxicants that were identified under **Health and Safety Code section 25249.8(b)** ([http://www.oehha.ca.gov/prop65/policy\\_procedure/listde051007.html](http://www.oehha.ca.gov/prop65/policy_procedure/listde051007.html)).
- IARC. Chemicals included should be those classified as Category 1. (<http://monographs.iarc.fr/ENG/Classification/index.php>)
- NTP CERHR. Chemicals included should be those identified as Serious Concern for reproductive/developmental toxicity. (<http://cerhr.niehs.nih.gov/index.html>)
- EU Classification. Chemicals included should be those previously classified as Category 1 under Annex I of Directive 67/548/EEC and now in transition to be classified as Category 1A under Annex VI, part 3 of Regulation (EC) 1272/2008. (<http://ecb.jrc.ec.europa.eu/classification-labelling/>)
- EU's Registration, Evaluation, Authorisation and Restriction of Chemicals' (REACH) Substance of Very High Concern (SVHC). SVHC is a list of substances in Annex XIV subject to authorization under Regulation (EC) No 1907/2006 of the European

Parliament concerning REACH. Chemicals recommended as Candidates to be Substances of Very High Concern in the EU's REACH Program which will include reproductive and developmental toxicants and carcinogens.

Chemicals identified from the above sources or portion of sources with noted concerns should not be included in the CSPA. Eliminating the chemicals from these sources and relying on the appropriate sources will help to generate a more focused and proper list of Chemicals of High Concern with “known” hazards as envisioned in the Statute. Using these general criteria will help generate a more focused and applicable list of CHCC.

### **Endocrine Disruption**

The CSPA statute includes chemicals known to cause disruption of the endocrine system as one of the criteria for chemical selection. As evidenced by the lack of any currently validated protocols to evaluate of substances for their endocrine disruption potential, it's clear that this is a field of science that is in relative infancy compared with other toxicology endpoints. In addition, the relationship of human diseases to the endocrine system is poorly understood and scientifically controversial. As described in the section above, the EU source list for these chemicals had no deliberative scientific review or decision-making by EU Authorities and no input by stakeholders. It does not represent any level of scientific consensus. The fact that a contemporaneous review by the EU's Science Advisors (CSTEE) determined that it did “not find the source material, methodology and selection criteria used to be scientifically adequate” and concluded “that there are important shortcomings in the present approach” makes clear that this is not a reliable source for CSPA decisions. Regulatory action, including reporting requirements under CSPA should not be based on individual studies or hypotheses that use un-validated methods, do not conform to comply with Good Laboratory Practices, and that otherwise fail to meet the basic expectations for adequate regulatory science.

The draft list includes 13 substances that are present solely due to their classification as potential endocrine disruptors. These 13 substances should be removed from the initial draft list, until more reliable assessment techniques or consensus conclusions are available for evaluating endocrine disruption potential and its relationship to health outcomes. The Department should look to the results on validated protocols from EPA's Endocrine Disruptor Screening Program's (EDSP) Tier 2 Testing. The United States EPA is at the forefront of developing a testing program that can serve as the basis for chemical prioritization and potential risk management efforts. EPA has been developing the protocols for the EDSP for 12 years. The EPA approach involves a Tier 1 battery of assays to detect for the potential of a substance to interact with the endocrine system. Depending on the results of Tier 1, a substance may go through a second battery of tests (Tier 2) that are designed to establish dose-response relationships for adverse effects. EDSP uses a Weight of Evidence approach to determine both the potential to interact with the endocrine system and whether any adverse outcomes have an endocrine-related mode of action.

### **Specific Chemicals**

Based on our concerns for chemical selection noted above, GMA believes that the following chemicals have been improperly included in the Preliminary Draft List and respectfully requests their removal from the reporting program.

- Butyl, ethyl, methyl and propyl paraben and 4-hydroxybenzoic acid. These chemicals should be excluded from the list because the only hazard information that supports their listing is from the EU Endocrine Disruption information. As described above, the EU Endocrine Disruption information should not be used in any circumstances. These are intentional ingredients approved for use by FDA in pharmaceuticals, food, and cosmetics and for the same uses in Europe at controlled levels in product as preservatives to prevent health risks from microbiological contamination. Further, methyl and propyl paraben are present in the FDA GRAS list, evaluated but the Select Committee on GRAS Substances as category 1, which is defined as meeting the following: *“There is no evidence in the available information on [the substance] that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or might reasonably be expected in the future”*
- Diethyl phthalate. This chemical should be excluded from the list because the only hazard information that supports this listing is from the EU Endocrine Disruption information. As described above, the EU Endocrine Disruption information should not be used in any circumstances.
- Bisphenol A (BPA). This chemical should be excluded from the list on the following basis. The Dev. & Repro. Determination should be, under the Department’s ranking system, downgraded to “Bad”. First, BPA was reviewed in 2010 by the Prop 65 DARTIC and they declined to list it. Second, as described above, the WA DEP’s approach to ranking CERHR findings should follow the actual classification used by the authoritative body, as it did in the case of every other source. To be consistent, CERHR’s rankings should be applied directly as are all rankings from all other sources and the logical approach, following rankings for other systems, would be that the determination for the substance would be downgraded to “Bad”. Lastly, as described above, the EU Endocrine Disruption information should not be used in any circumstances.

### Trigger Levels

GMA is very concerned about the trigger level reporting ranges specified in the Preliminary Draft Rule. The 1/22/2010 draft of the rule indicated that a reporting trigger level would be identified for each chemical with the expectation that it would be based on science and potential for health concerns, a sensible scientific approach to the matter. DoE’s “Phase 3 Report” states, *“Concentration of chemicals of concern present at 0.1% in product components (1000 ppm) is a commonly accepted value, used by jurisdictions such as the European Union, to indicate that a chemical is intentionally added to a product”*. The Preliminary draft seems to suggest reporting required for every chemical at concentrations above 10 parts per million. There is no appropriate public health protection rationale for such a uniform and onerous requirement, and no explanation or justification for why the Department moved away from its earlier policy.

As noted in the Phase 3 report, there are existing resources in other regulatory systems that Washington could use as guidance in developing a system protective of public health, including endpoint-specific cutoff values articulated in the Global GHS guidance materials (which explicitly

discuss adjusting thresholds) or those used by other countries in their GHS-based classification and labeling programs. For instance, under the EU's GHS Classification and Labeling program the de minimis trigger level is 0.1% in a product (1000 ppm) unless a different level is identified based on a health risk assessment (<http://ecb.jrc.ec.europa.eu/classification-labelling/>). The EU Cosmetic Directive contains specific threshold levels for over 300 chemicals that range between 0.001% and 25% (w/w) ([http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/index\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/index_en.htm)). In Proposition 65, California has developed chemical specific exposure limits. Washington should follow a harmonized pathway in implementing this reporting system to help maintain consistency throughout the regulating and regulated communities.

Consistent with the Phase 3 report dated 23 July 2010 submitted to DoE, GMA recommends the use 0.1% (1000 ppm) as a default reporting trigger, adjusted if appropriate to apply health-based, chemical specific trigger levels based on the specific hazard levels in the listed chemicals as envisioned in the 1/22/2010 draft. GMA strongly encourages the Department to return to the earlier policy.

### **Intentionally Added**

There is currently no definition or concept of "intentionally added" included in the Preliminary Rule; however, the Act implies that its application is to intentionally added chemicals only, since it calls for chemical information such as CAS number, description of the chemical's function in the product, the amount used, etc. This means that only intentionally added chemicals should be covered by the reporting requirements. Additionally, the Department of Health (DoH)/University of WA Report, dated 23 July 2010 submitted to the DoE (Task 1, C; page 4) indicates: "...27 chemicals on the list are probably not added as ingredients during final production of children's products." They seem to further suggest that these chemicals will be excluded when they state: "The broad definition of "intentionally added" proposed by Ecology should cover the range of these chemicals in children's products. It also acknowledged in the "Phase 3 Report" that ***"the focus should be on those chemical that are intentionally added to children's products"***. GMA agrees with this statement as focus of activity for the Rule. As stated above, the "Phase 3 Report" clearly indicates that 0.1% is a valid threshold for determining that a chemical is intentionally added. GMA strongly encourages the Department to modify the regulation and to focus reporting only on chemicals that are intentionally added to children's products to serve a functional purpose

### **Confidential Business Information**

GMA is pleased to see that the draft rule contains provisions that will protect Confidential Business Information (CBI) from disclosure to competitors. This is a critically important aspect of this program. To ensure that submitted CBI is in fact protected from release, we encourage the Department to develop strong procedures so that submitters can be certain that their trade secret information will be adequately protected.