



BY E-MAIL TO JOWI461@ECY.WA.GOV

**TO: JOHN R. WILLIAMS, JR.
WASHINGTON DEPARTMENT OF ECOLOGY**

**FROM: FRANCES WU, ASSOCIATE GENERAL COUNSEL
PERSONAL CARE PRODUCTS COUNCIL**

RE: CHILDREN'S SAFE PRODUCTS ACT RULEMAKING; ADVISORY GROUP PHASE

DATE: 9/23/09

Enclosed below are responses of the Personal Care Products Council to questions posed to the advisory group. Please do not hesitate to contact me if you have any questions. I can be reached at wuf@personalcarecouncil.org or 202.331.1770 x495.

I have asked our members whether they would be willing to participate in the pilot and will let you know their response. We look forward to working with the Department on this rulemaking effort.

Thank you.

1) Issues associated with the 'reporting list' – the list of chemicals that triggers reporting by manufactures.

- a) How many chemicals should be on the reporting list? How should they be selected or prioritized? Should the selection process be specified in the rule? Should there be allowance for chemical exemptions such as Generally Recognized As Safe (GRAS) chemicals? See <http://www.foodsafety.gov/~dms/eafus.html> for list of chemicals.**

The selection process should be specified in the rule, so that stakeholders can have predictability for future additions to the list. A number of categorical exemptions from the list are appropriate, given the U.S. FDA's jurisdiction over and approval of such substances, including without limitation: 1) those substances that are "generally recognized as safe" for use in food; 2) approved food and color additives; 3) any chemical that has been reviewed and approved by the FDA for use as a drug, including either a new drug or an OTC monograph drug; and 4) any inactive ingredients that have been approved by FDA as part of a new drug application. Those ingredients designated as "safe" for cosmetic and personal care use by the Cosmetic Ingredient Review should also be exempt.

We agree with the Department's position in its July 2009 report that prioritization should be based on a risk assessment that takes into account not only the hazard factors identified in the law, but, importantly, exposure and toxicity. We also agree with the Department's decision to eliminate those chemicals from consideration to which children will not or are unlikely to be exposed.

- b) Should chemicals that are not ordinarily used in consumer products be excluded? If so, how do we know what chemicals are not ordinarily used? For example in a recent study tetrachlorethylene and 4-nonylphenol were found in some children's products.**

We agree with the Department's preliminary judgment that 50 chemicals is sufficient for purposes of reporting under this law, and any listed chemicals should be used in consumer products. To include other chemicals is pointless, as illustrated by the suggested list of nearly 800 chemicals under the California Safe Cosmetics Act, only a small fraction of which is actually used in cosmetics.

- c) For this list of issues 'de minimis' means the amount of a substance in a product which would trigger reporting. Should there be a 'de minimis' value for the chemicals on the reporting list? If so, what should it be based on? Should United States National Toxicology Program (US NTP) See - <http://ntp.niehs.nih.gov/>, Consumer Product Safety Commission (CPSC) See- <http://www.cpsc.gov/> and EPA exposure limits be used? Should the de minimis level be based on something other than risk, such as detection limit?**

Reporting should be based on risk assessment, not on detection limits. Basing reporting requirements on the detection limit is an unsustainable practice. The limit of detection is ever improving; what once was detectable at ppm is now detectable at ppq. Detectability does not ascertain risk.

Under "risk-based" chemical regulation, chemicals are prioritized for regulatory action based on defined characteristics. The four components of risk assessment - hazard assessment, dose-response, exposure assessment, and risk characterization - are part of the process. If, using a "weight of evidence" approach, a substance meets appropriate hazard criteria, then an exposure assessment is conducted, followed by risk characterization to determine if risks are adequately controlled. This procedure is described in U.S. EPA documents (U.S. EPA. Guidelines for Carcinogen Risk Assessment (2005). U.S. Environmental Protection Agency, Washington, DC, EPA/630/P-03/001F, 2005.; Clegg, E. D., C. Sakai, AND P. Voytek. Assessment of Reproductive Risks (Journal Version). U.S. Environmental Protection Agency, Washington, D.C., EPA/600/J-86/501). Similarly, the European legislation specifies a risk assessment procedure for each chemical so risks can be compared and chemicals prioritized for regulatory action. (http://guidance.echa.europa.eu/chemical_safety_en.htm). Such an approach acknowledges that specific chemical exposures subject an individual to a continuum of risks based on the potency of the chemical to cause toxic effects and the magnitude of the exposure to the target tissue and allows for comparative risk and risk-benefit analyses.

Threshold levels must be determined using scientific risk assessment methods. A model that could be adapted is the safe harbors for California's Proposition 65, which includes numerical limits, as well as routes of exposure.

d) If a reporting list is in the rule, should the list also include the 'de minimis' limit? If the 'de minimis' value is in the rule, how would we deal with situations where new information shows that it should be adjusted?

Without a "de minimis" reporting limit, manufacturers are subjected to using the current detection level as a surrogate "de minimis" reporting level, and as noted above, detection does not translate to lack of safety. Again, we believe threshold levels for reporting should be established using the established scientific risk assessment methods described above.

e) Can the public recommend that chemicals be removed or added to the reporting list? If so what should the process be? What criteria and timeline should the agency use to make a determination or decision to add or remove a chemical? Should these criteria be in the rule? Should a reasonable toxicological risk assessment be mandated as a contingent requirement for adding or removing a chemical? Can we base such decisions on hazard assessment alone?

The public should be able to make recommendations to the body maintaining the list in a clear and transparent manner. The timeline and criteria should be based on an assessment of likely risk to the consumer. If timelines alone drive decisions, decisions are likely to be made in the absence of data or based on inadequate data.

Modification of the list should be initiated on the basis of risk assessments and strong scientific evidence.

f) Is there a need to benchmark Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH) see - http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm or Restriction of the Use of Certain Hazardous Substances (RoHS (Europe)) see - <http://www.rohs.gov.uk/> or similar regulated chemical listing process as to who can add or remove chemicals from the prioritized list? Specifically is there a need to review current REACH or/and ROHS chemical criteria and prioritization lists as well as chemicals assessment approach for hazards/risks/exposure to determine if there are any cross-over applicability?

While there is considerable merit to compiling complete information on chemicals, as REACH attempts to do, prioritization should be done on the basis of risk assessment, rather than the volume of chemicals in commerce.

g) What should be the process for triggering the modification of the list after comments from the public? How is this one different from e)?

h) What should be the frequency for modifying the reporting list?

Any modifications to the list, regardless of how initiated or by whom, should be evaluated on the basis of risk assessments. See answer to 1(e) above.

i) How should the reporting list of chemicals be prioritized? Should the chemicals on this list be prioritized by importance to be phased out/banned? - Should prioritization be based upon a strict toxicity measure of a standard exposure level to a set number of children, and which ones cause the most harmful effects? Or upon which chemicals are the most prevalent among those children are exposed to? Or which toxic chemicals are found at the highest levels in which children's products? Or, which high priority chemicals are found in the most popular children's products?

j) Should the sources for identifying high priority chemicals (EU, REACH, California, Canada, et al.) be included in the rule? If not, would it just be included in the final report and available on the DOE website?

The selection process should be specified in the rule.

k) Should there be some high priority chemicals for which there is no 'de minimis' value, i.e., zero amount can be intentionally added to the production of a children's product? What would be the method to identify what is intentionally added? What about chemicals that are not intentionally added but are present in the product due to manufacturing processes or contamination?

As noted in our responses to 1(c) and 1(d) above, risk assessment, not detection, should be the relevant methodology. For children's cosmetic products, only ingredients listed on the label qualify as "intentionally added." "Incidental ingredients," as defined by FDA, and trace elements should be excluded. Incidental ingredients have been defined by FDA to include "substances that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient." 21 C.F.R. § 701.3(l). FDA has excluded incidental ingredients from having to be labeled on cosmetic products, for the reason that their concentrations, if any, are so small and insignificant as to have no effect in the finished product. For similar reasons, the California Department of Public Health has adopted the FDA definition of "incidental ingredient" for purposes of the CA Safe Cosmetics Reporting Act, and has excluded incidental ingredients from the scope of reporting.

l) How should Ecology/DOH weight the value of the REACH list compared to Canada or California's lists in coming up with our own list?

WA state should develop its own list, based on risk assessment, as discussed above.

m) What do we mean by "children's products?" Should we more precisely/carefully/narrowly define the universe of children's products to be covered by reporting? It would be good to make sure we are all talking about the same products. Are there some products that we are missing? See California's draft cosmetics reporting form to get an idea of how they have defined the universe of cosmetics products.
<http://www.cdph.ca.gov/programs/cosmetics/Pages/faq.aspx>

The definition of "children's product" in WA's law is dissimilar to that of the Federal Consumer Products Safety Act. [15 U.S.C. § 2052], in that it expressly includes "children's cosmetics." By contrast, cosmetics are excluded from the definition of "consumer product," and hence, from the definition of "children's product," under the federal CPSA. Nonetheless, we believe the definition in the WA law can adopt the intended for "12 years of age or younger" standard in defining what is a "children's product."

The definition for cosmetic should be the same as that set forth in the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321].

n) Should reporting be limited to chemicals known to be used in manufacturing or should it also include chemicals known or likely to be present due to common contamination?

Chemicals that are not intentionally added and have no functional purpose – including "incidental ingredients" as defined by FDA and trace elements - should be excluded from the department's determination, as stated in our answer above to 1(k). Given that the priority list will contain around 50 chemicals, we believe the Department should focus its resources on only on those chemicals that are intentionally added to products, and hence, provide greater exposure to consumers.

2) Issues associated with the reporting process

- a) **How should confidential business information be reasonably treated?**
- b) **What should be the timeline for reporting? (who should have to report on what, when?) Should there be a phased-in approach? If so, what should it be based on? How would it work? Which companies, for which materials or substances should be required to report first?**
- c) **What information and format must a report contain? Is there any reason to allow submittal of hard copy, rather than electronic, data?**
- d) **Should there be a standardized mechanism for reporting (i.e. companies are required to fill out a standardized form for each chemical etc.)? This may help minimize time trying to translate information to the public.**
- e) **What should be done with the information reported to Ecology? Options range from releasing information upon request to actively putting it in the public eye – i.e. post it on a website, do press releases, etc.. Should the way the information will be handled be in the rule? Should information be provided in a manner that clearly communicates exposure risk or the lack thereof? Should these options be in the rule?**

Reported information should not be actively put in the public eye, e.g., through a publicly accessible database. There is no indication that the legislature intended such a result, and members of the public should be required to submit requests for information through the standard records access processes. That said, if a decision is made to actively put data in the public domain, then there should be a mechanism that permits companies to provide readily accessible risk information about reported products/ingredients.

- f) **How can a chemical or material manufacturer determine if their product has a chemical from the reporting list? - Testing, Self-certification or Self-declaration of conformity, documented oversight process to ensure none of the chemicals are used at any point in the production process, etc.. If we allow something other than testing results to be submitted, what information must be included in the report?**

Finished product manufacturers are obligated under the federal law to know the ingredients in their products. In the case of cosmetics, these ingredients are set forth on the product label. The only exception is flavors and fragrances, and finished product manufacturers can obtain this information from their suppliers.

Regarding discussion at the September 9, 2009 meeting on whether and how suppliers (chemical manufacturers) should report, we would note the following points. First, as several attendees pointed out, the statutory burden and obligation for reporting lies with the manufacturer of a product (or alternatively authorizes a company's trade association to submit reports). The process for reporting under the California Safe Cosmetics Act has just begun, so our member companies are in the process of evaluating workability of the online reporting system. It bears noting, though, that suppliers are only identified in the report by their downstream customers (manufacturers) where the supplier is unwilling to

divulge to the customer (typically for proprietary reasons) – or the manufacturer is otherwise unable to obtain from the supplier – the specific chemical content or composition of the supplied component(s). In such circumstances, the agency would contact the identified supplier to obtain the information directly from the supplier. We believe this is a sensible and streamlined approach. To have suppliers furnishing the information to the agency on their own volition could prove unwieldy. Manufacturers are ultimately responsible for knowing the content of their products.

g) Is there a need to benchmark Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH) see - http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm or Restriction of the Use of Certain Hazardous Substances (RoHS (Europe)) see - <http://www.rohs.gov.uk/> or similar regulated reporting process? If we allow something other than testing results to be submitted, what information must be included in the report? Specifically is there a need to review current REACH or/and ROHS reporting process to determine if there are any cross-over applicability?

h) How should Ecology summarize and analyze reported data that is submitted by manufacturers? Should information be analyzed by products or types of products? Should this work feed into revising the reporting list?

3) Issues associated with enforcement of the CSPA

a) How should the reporting requirements established by the rule be enforced?

b) What should trigger a penalty? Should the agency provide notice and opportunity to comment prior to issuing a penalty?

c) Should the media be informed?

d) Should Ecology independently test products to ensure compliance with the law?

e) What methods (audits, inspections, objective evidence)? should Ecology use to ensure that manufacturers are compliant with the reporting requirements of the CSPA?

f) Should labeling be considered? For example: If a product contains one or more reporting chemical, it gets labeled in some way - such as some cautionary language a la Prop 65.

The question was posed at the September 9 meeting, what constitutes a violation of the law? Violations should not be based on number of units, but on the number of chemicals at issue. We agree with the comments made at the meeting that the company should be afforded a chance to work with the agency and present its justification for its decision prior to the imposition of any penalty.

Moreover, additional labeling requirements are not necessary to ensure safe products for consumers. In the case of cosmetic products, as noted above, the Federal Food, Drug, and Cosmetic Act requires each cosmetic to include an ingredient declaration on the product label.