August 23, 2012

Peer Review
Chapter 55. Safe Consumer Products
Proposed Regulations, R-2011-02

Jennifer Sass, Ph.D.
Senior Scientist, Natural Resources Defense Council (NRDC) and,
Professorial Lecturer, George Washington University
NRDC, 1152 15th St NW, Ste. 300, Washington, DC 20005
Email: jsass@nrdc.org; Tel: 202-289-2362

Thank you for the opportunity to provide scientific peer review for the Safe Consumer Products Proposed Regulations.

I am concerned that there is no requirement for the DTSC to update the Chemicals of Concern (COC) list on a regular basis. The first list will consist of approximately 1,200 chemicals, enough to keep the Department busy for a few years I'm sure, as the program gets established. However, without statutory deadlines for updating the COC list it may soon fall into disuse. Its value is in providing current information to the public about contaminants in consumer products. Therefore, having mandated deadlines for regular review and revisions will be critical to its function, and I strongly recommend that such deadlines be added.

My response to the specific points for which the Department requested comment are below:

1. The use of chemicals lists developed by the sources named in the regulations identifies chemicals with hazard traits that have public health and environmental concerns to produce an initial Chemicals of Concern (CoC) list. (Article 2, §69502.2)

Summary - I strongly support the list of resources that are named to identify chemicals that should be on a Chemicals of Concern list. Most are well-known and frequently-referenced chemical lists that have undergone considerable public vetting and often also peer review and opportunities for public comment.

Recommendation - DTSC should consider including all IRIS chemicals, not just those with RfD or RfC limits based on neurotoxic endpoints. It is not clear to this reviewer why the current form of the regulations states that only neurotoxic endpoints will be considered. §69502.2(1)(E). There are many chemicals that have been assessed by IRIS and assigned an exposure limit, RfC or RfD, based on health impacts other than neurotoxic endpoints, such as organ toxicity, immune toxicity, reproductive toxicity, etc. These should also be candidates for the Chemicals of Concern list. While neurotoxicity is a sensitive endpoint of concern, other endpoints are just as scientifically valid.

General comments-

I agree that chemicals that are listed in the NIEHS Report on Carcinogens (RoC) are good candidates for the Chemicals of Concern list. These are chemicals that have been identified as "known" or "reasonably anticipated" to be carcinogenic to humans. The ROC follows an extensive multi-step chemical evaluation process that includes independent external peer review, expert advisory reviews, and ample opportunity for public comment. The science staff that develops the ROC conducts extensive reviews of the scientific literature that includes three interagency reviews, six opportunities for public comment, and two external expert scientific reviews including one by its Board of Scientific Counselors which represents industry, government, and academic scientists. The ROC listings meet the standard of scientific excellence on which scientists and regulators rely.

I agree on listing carcinogenic chemicals from IARC Monographs Groups 1, 2A, and 2B. It is important to include the chemicals that are probably (2A) and possibly (2B) carcinogenic to humans because if we do not take seriously the evidence from animals and mechanistic studies, then we are waiting for evidence in humans (Group 1), and this represents a failure to prevent harm to people. Human evidence means cancers in people, and those data points represent someone's mother or father, someone's brother or sister, someone's wife or husband, or even a son or daughter. Waiting for chemicals to become Group 1 carcinogens means waiting for toe tags and death certificates, and California is correct to do better than that at preventing cancer.

I agree on relying on the listing of reproductive and developmental toxicants from the National Toxicology Program, Office of Health Assessment and Translation (OHAT). This sturdy new program is following a transparent and scientifically-credible process of substance review, with an excellent track record of productivity. I am very pleased that the work of this office will be relied upon to identify Chemicals of Concern.

2. Use of the initial product prioritization criteria in the chemical and product prioritization process in Article 3 are sufficient to identify all types of consumer products with CoCs as potential Priority Products. Use of the key prioritization criteria considers those critical factors which identify the potential Priority Products during the initial phase as high priority. (Article 3, §69503.2)

Summary - I support use of the factors in the lists identified in this section as a means of evaluating products to determine the adverse impacts and exposure associated with the product: adverse impacts and exposures. Inclusion of markets and sales data is a very good idea; this information should be made public.

General comments-
I agree with documenting both the adverse impacts and the exposures. This information will be very helpful for prioritizing products with some consideration of real-world risks. The list of characteristics to be considered includes aggregate effects, cumulative effects, physicochemical properties, and environmental fate. This is a reasonable and scientifically-defensible list, consistent with other state and federal chemical assessment approaches including those that address pesticide risks.

I agree with consideration of sensitive populations, habitats, and impaired ecological areas. This approach to assessing impacts is necessary to prevent "hot spots" of contamination or populations that are disproportionately impacted by Chemicals of Concern. Failure to have included these considerations would be a violation of Environmental Justice considerations, and unjustifiable.

Inclusion of markets and sales data is a very good idea, and will prove useful for developing chemical distribution information. As much as possible, this information should be made public so that it can be used by other federal, state, and local officials, scientists, medical professionals, and advocacy groups. For example, it may be useful to epidemiologists looking at potential relationships between product exposures and health impacts, or for unions and worker advocacy groups looking at the prevalence of various cleaning products likely to be used by janitorial staff across the state. While these are just hypothetical examples, they are suggestive of the ways that these data may be useful to the public.

I am pleased that product uses, discharges, disposals, and any contributions to end-of-life impacts will be considered. Consideration of these life-cycle factors will make the assessment of impacts more realistic.

3. The principles outlined in the proposed regulations that will allow the department to develop Alternative Analysis Threshold based on best available technologies is scientifically understood. (Article 3, §69503.5)

This section is scientifically understood, is robust and is comprehensive enough to allow the department to develop scientifically-defensible alternative analysis thresholds for chemicals of concern. However, whether or not the science is available to be able to develop a threshold for each chemical will depend on the chemical, or class of chemicals, and it is hard to predict how flexible this will be to future chemicals. In addition, it seems to require a rather rich database in order to conduct a reliable analysis and identify a threshold. I think this may be challenging for some chemicals or classes of chemicals. The department is wise to identify critical properties like inherent potency, the ability to bioaccumulate, the unintended presence body tissues, and the disproportionate impact on sensitive populations or habitats. These critical properties provide guide posts for meaningful assessments of the impacts of chemicals, even when little is known of their toxicity.

4. The definitions of the various "adverse" impacts and general usage of the term "adverse" impacts is used throughout the regulations. Within the context of the definitional and general use of the term "adverse" impacts in the regulations and when scientific information is available, a qualitative or quantitative determination of adverse impact can be made, and is adequately protective of public health and the environment. (Article 5, and Att 6 § 69301.2(a)(3)-(10))

Summary - I agree that the contextual use of the term "adverse" throughout the regulations is adequate, and will allow a determination of adverse impacts, quantitative or qualitative. I recommend that chemicals on the EPA Contaminant Candidate List (CCL) for drinking water contaminants also be included. I agree with the approach of including byproducts degradates and reaction products of chemicals, including nanomaterials, to assess adverse impacts.

Recommendation - Where the proposed regulations list chemicals for which primary Maximum Contaminant Level (MCLs) have been established (§69301.2(a)(10)(3), I suggest also including chemicals listed on the EPA Contaminant Candidate List (CCL). The CCL is a list of contaminants that are not subject to proposed or promulgated federal primary drinking water regulations (they do not have an MCL), but for which EPA may require regulation under the Safe Drinking Water Act (SDWA). Chemicals on the CCL lists are ones for which scientific data show that they may have an adverse health effect on people and that they occur or are likely to occur in drinking water. There are 116 contaminants on the CCL 3 (the third list, published in October, 2009), which have undergone screening and expert review based on adverse health impacts and presence in drinking water. The list includes chemicals used in many

common consumer products including solvents, fragrances and skin lotions, as food additives, in pesticide products, in veterinary and human pharmaceuticals, in antifreeze, paints, metal polishes, explosives, dyes, and food packaging, to name just a few applications. The SDWA requires EPA to make a decision about whether nor not to regulate at least five of the contaminants on the CCL. However, since 1998 when the first CCL was published (CCL1) this glacially-slow process has resulted in no (zero) new MCL determinations (perchlorate is the first contaminant since 1998 that EPA determined it would set an MCL for, but to date an MCL for perchlorate has still not been finalized). Therefore, to make sure the Safe Consumer Products regulations are a reflection of current scientific understanding of the hazards and exposure to drinking water contaminants, the CCL list of chemicals should be included, and not just the MCLs which are rarely or never updated.

General comments-
The description of adverse ecological impacts is fairly comprehensive, and includes acute or chronic toxicity, impacts on aquatic or terrestrial ecosystems including damage to vegetation, and impacts on environments that have been designated as impaired. Adverse environmental impacts includes air quality, soil quality, water quality, ecological impacts, and violations of enforceable state or federal regulatory standards relevant to environmental protection. I agree with this approach.

Public health adverse impacts are specified to include occupational health, which is important because often the most severe health impacts are observed among occupationally exposed populations. I agree with this approach.

The description of adverse is correct to include, “adverse waste and end-of-life impacts”, which includes the byproducts, degradates and reaction products generated during the life cycle of the Priority Product, and each alternative. This is a very critical inclusion for realistic and meaningful assessments of adverse impacts from materials and products. For example, nanosilver, which EPA has recently approved as a potent biocide for use in textiles including children’s clothing and bed sheets, degrades into silver ions which are highly toxic to aquatic ecosystems. Failure to consider byproducts degradates and reaction products of chemicals like nanosilver would be a failure to assess adverse impacts. Similarly, consideration of discharge into storm drains or sewers is a significant concern for nanosilver, which has been shown in some studies to adversely impact the beneficial microbes necessary to treat sewage. Taking such data into account is important for a meaningful assessment of adverse impacts.