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SUBJECT: EXTERNAL PEER REVIEW FOR SAFER CONSUMER PRODUCT ALTERNATIVE REGULATIONS BY TERRY COLLINS

I have read as requested the full draft proposed regulations in Attachment 4 and the portions that call for chemical of concern, priority products, and alternatives analysis in attachment 3 and have made use of the explanatory information in Attachment 5.

I will begin my review with an overview statement for each requested discussion point and then, when necessary, proceed to a critique of specific details.

1. Use of chemical properties, toxicological information, volume of the chemical in commerce, and adverse impact to sensitive subpopulations, public, and the environment to develop supporting rationale and prepare Chemicals Under Consideration and Priority Chemicals of Concern (COC) lists.

Overall, I find the draft the Safer Consumer Product Alternative Regulations to be well conceived, scientifically sound (with specific exceptions as below) and precisely explained procedurally. I have the following specific points to make:

- [Minor Point] P1L13 alternatives assessment introduced as if defined (maybe give page reference).

- P5L20 I make the following point for scientific reasons. While economic and technical factors are procedurally important in an alternative introduction, the introduction of “technologically and economically feasible” in the guiding principles section and the follow-ups (pp 17, 55, 58), if accepted, could

weaken the scientific basis on which the regulations are proposed to be going to stand because these could subjugate the scientific basis for acting on a Priority Chemical or Priority Product to economic factors which are not properly part of an objective science-based analysis of the risk to public health and the environment. Even given the next principle (P5L21), the current language carries too much risk of subjugating science to economic factors. Therefore, I recommend changing “to the extent technologically and economically feasible” to “where technological and economic factors are weighed against risks to public health and the environment”.

In all appropriate sections, it could be a good idea to have economic and technical feasibility information filed as appendices to AA reports rather than as parts of the report proper.

- P6L21 “Bioaccumulation” is the net accumulation of a chemical substance in an organism or part of an organism, or an environmental compartment, that absorbs the chemical at a rate greater than that at which the chemical is lost.”

  This is an odd definition. Bioaccumulation is a process (“accumulation”), not a quantity (“net accumulation”)—there are many definitions and some are confusing. The rates of sequestering of a chemical from the surroundings into an organism and the rate of loss from the organism are not constant over time and may reach a point where they are identical. Before exposure, when no chemical substance is present, the rate of sequestration and loss are obviously both zero. Upon exposure, the initial overall rate of entry is dependent on the concentration in the surroundings and will be faster per unit time the higher that concentration. As soon as some chemical substance has been sequestered, the exiting process can begin—the rate of exit is dependent on the amount of chemical in the organism—more chemical, faster rate. Upon initial exposure, the chemical being sequestered by an organism will begin to accumulate at a rate greater than that at which it is lost and will partition to different parts of the organism at differential rates. The concentration of the substance in the organism will continue to increase to the point that the system reaches a steady state at which point the overall rates of sequestration and loss will be equal, but there will be a steady state concentration in the organism higher than in the surroundings. The point is that the discussion of different rates as the foundation of the definition makes it imprecise, even if such rates are often invoked in this way. The use of rates is appropriate as explanatory considerations as, for example, in the USGS definition discussed below, where the fact that the rates must change with time as the chemical builds up in the organism is not undermined by the language employed.

Where does “environmental compartment” come from? Is there precedent for piggybacking “environmental compartments” on bioaccumulation? The USGS definition is excellent. Why not rethink what you are trying to achieve around the USGS definition. Related terms are also defined.

http://toxics.usgs.gov/definitions/bioaccumulation.html
Bioaccumulation
“Bioaccumulation is a general term for the accumulation of substances, such as pesticides (DDT is an example), methylmercury, or other organic chemicals in an organism or part of an organism. The accumulation process involves the biological sequestering of substances that enter the organism through respiration, food intake, epidermal (skin) contact with the substance, and/or other means. The sequestering results in the organism having a higher concentration of the substance than the concentration in the organism’s surrounding environment. The level at which a given substance is bioaccumulated depends on the rate of uptake, the mode of uptake (through the gills of a fish, ingested along with food, contact with epidermis (skin), …), how quickly the substance is eliminated from the organism, transformation of the substance by metabolic processes, the lipid (fat) content of the organism, the hydrophobicity of the substance, environmental factors, and other biological and physical factors. As a general rule the more hydrophobic a substance is the more likely it is to bioaccumulate in organisms, such as fish. Another way of saying this is that bioaccumulation of a substance is correlated to the octanol-water partition coefficient (K_{OW}) of the substance. Increasing hydrophobicity (lipophilicity) leads to an increasing propensity to bioaccumulate. Some substances do not conform to this relationship, such as methlymercury. Methlymercury accumulates in fish to a much greater degree than methlymercury’s K_{OW} would indicate.
A related term is bioconcentration. Bioconcentration differs from bioaccumulation because it refers only to the uptake of substances into the organism from water alone. Bioaccumlation is the more general term because it includes all means of uptake into the organism.”
Biomagnification is discussed here:
http://toxics.usgs.gov/definitions/biomagnification.html

So here is my suggestion for a modification to your definition, which takes further key elements from the USGS definition:

LONGER: “Bioaccumulation” is the accumulation of a chemical substance in an organism or part of an organism. The accumulation process involves the biological sequestering of substances that enter the organism through respiration, food intake, epidermal (skin) contact with the substance, and/or other means. The sequestering results in the organism having a higher concentration of the substance than the concentration in the organism’s

surrounding environment. The level at which a given substance is bioaccumulated depends on the rate of uptake, the mode of uptake (through the gills of a fish, ingested along with food, contact with epidermis (skin), …), how quickly the substance is eliminated from the organism, transformation of the substance by metabolic processes, the lipid (fat) content of the organism, the hydrophobicity of the substance, environmental factors, and other biological and physical factors."

SHORTER: "Bioaccumulation" is the accumulation of a chemical substance in an organism or part of an organism. The accumulation process involves the biological sequestering of substances that enter the organism through respiration, food intake, epidermal (skin) contact with the substance, and/or other means. The sequestering results in the organism having a higher concentration of the substance than the concentration in the organism's surrounding environment."

- P7L19 ""Chemical mixture" means a mixture or solution of two or more chemical substances." This might be better encompassing as "Chemical mixture means a mixture of two or more chemical substances in any solid, liquid, or gas, or any other phase of matter".

- P8L33: This definition is confusing: "Chemical substance" means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition."

  Do you mean that "any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition" is to be considered part of the chemical substance? Or are you stating that these species are to be considered chemical substances in their own right that play roles in the decisions of whether a chemical becomes a chemical of concern or a priority chemical?

  While I see the rationale, I do not think it is a good idea to conflate "chemical substance" with "stabilizers and other necessary additives as well as impurities". Also, I don't think solvents should be excluded because they may not be completely removed and they may be toxic. Since you are setting this general term up for your own objectives, maybe you can be explicit on that by including some of your own defined language:

  SUGGESTED CHANGE: Chemical substance" means any chemical

element or any of its compounds in the natural state or obtained by any manufacturing process which for the purposes of determining its status as a chemical of concern or a priority chemical will be evaluated jointly with any other chemical substance that is a necessary additive to preserve stability and/or determine properties (including but not limited to antioxidants, antimicrobials, antistatic agents, chemical blowing agents, flame retardants, heat stabilizers, impact modifiers, lubricants, light stabilizers, plasticizers, fillers, or colorants) and any impurity deriving from the process used (including but not limited to solvents, catalysts, reagents, or byproducts).

- P11L12 on:
  (37) "Greenhouse gas" means any of the following gases:
  (A) Carbon dioxide.
  (B) Methane.
  (C) Nitrous oxide.
  (D) Hydrofluorocarbons.
  (E) Perfluorocarbons.
  (F) Sulfur hexafluoride.
  (G) Nitrogen trifluoride.

  Ozone is a very important greenhouse gas—probably should be added: http://en.wikipedia.org/wiki/Greenhouse_gases

  And what about the other members of the IPCC list such as the halons? http://en.wikipedia.org/wiki/IPCC_list_of_greenhouse_gases

- P36L17–24: This is clearly an important section. I recognize you have to start somewhere and I think the choice of hazard traits for the initial list is excellent, but you could capture some low hanging fruit by adding neurotoxicants here because there is little or no debate for specific toxicants in this category—e.g., lead, and the adverse impacts on public health and the environment have been and could continue to be large. This might help you establish the initial list with more scientific authority and less controversy. Suggestion: "(1) Chemicals that are carcinogens or reproductive toxins, or both, or neurotoxins as defined in section 69301.2(a)(9).

2. Use of consumer product marketing, potential for exposure of the Priority Chemical COC in the consumer product to the public or contamination to the environment, to develop supporting rationale and prepare a list of Products Under Consideration and Priority Products.

Overall, I find DSTC's approach to evaluate consumer products that contain a COC and prioritizing these products as Products Under Consideration and Priority

Products with the following consumer product information: COC exposure to the public or environment from the consumer product, volume of consumer product, product uses that may cause harm to public health or releases to the environment, presence of the chemical in the environment, to be thorough and logical, but recommend the following be considered as the Final Regulation is drafted.

- General comment on **§ 69302.3. Chemicals Under Consideration** with wider applicability to the whole regulation. The treatment of prioritization factors does not include mixtures of hazardous chemicals. There is a growing body of evidence that the impact of exposure to multiple hazardous chemicals is more than additive. This is complex territory and there is so much more we need to learn. However, it is likely that adverse effects attributable to mixtures of chemicals, each at low levels, will be discovered with increasing frequency and it would be an improvement if this regulation could have some language in appropriate sections that recognizes the existence of the importance of mixtures and anticipates the likely growing importance.

  So, it would be an improvement to have some section or combination of clauses throughout to recognize that the presence of multiple priority chemicals in a product makes it a more serious prioritization issue. For example, if a product contains more than one priority chemical at de minimis levels, does this mark it being of more concern than if only one priority chemical is present? It likely should. This could be handled by closing the door on products containing more than one priority chemical with a clause, e.g., “at no time will a de minimis exemption be given for any priority product if that product contains more than one priority chemical”, and/or by other mechanisms to recognize the products with more than one priority chemical are of higher concern.

- A clause could be put in section **§ 69303.4. Priority Products** that the presence of more than one priority chemical in a product in a priority product would be a criterion for making it harder to gain an exemption. Again, the implications of mixtures touch on the entire regulation.

3. Use of human health and environmental impacts of the Priority Chemical COC in the Alternatives Assessment to develop safer consumer products.

Overall, I find the DTSC’s approach with specific human health and environmental impacts named and expanded upon from the law in the draft regulatory text to be thorough and logical.

I recommend the following change to the green chemistry section. For certain

hazardous chemicals, we are confronted with a dilemma when the chemical is both hazardous and is essential to society for its distinctive properties that are so compound specific that it cannot be replaced. Sometimes the hazard trait may be a key part of the value proposition. In these cases, trying to produce a green alternative is not a viable strategy or at least it is beyond our current level of science. Nevertheless, there could be excellent green chemistry approaches to reduce the adverse impacts. Thus, green chemistry approaches other than the production of safer alternatives are an important part of green chemistry and should be encouraged by the DTSC as one way to handle certain priority chemicals. So, for example, is ethinylestradiol, a key ingredient in the reproductive pill, going to be labeled a priority chemical? It is one of the most bioactive compounds we manufacture. It passes in part through the human body and through our waste treatment plants to contaminate natural waterways. It is a reproductive toxicant to certain breeds of fish at low ppt concentrations in water and such concentrations can often be found in our rivers and streams. Given that the properties, including the precise molecular shape and persistence, are key to its efficacy, how are we going to find a green substitute for ethinylestradiol? This dilemma confronts us with many hazardous chemicals including other key drugs. So what we should we do?

I recommend that the regulation should also explicitly encourage the development of green approaches other than alternatives and alternatives assessment such as the development of improved green remediation approaches for reducing and eliminating hazardous chemicals. You could incorporate this idea as follows:

- P72L12; (C) Requiring the responsible entity or manufacturer to initiate a green chemistry research and development project or fund a green chemistry challenge grant using green chemistry principles including both the pursuit of safer alternatives and, where safer alternatives are impractical, the use of green chemistry approaches aimed at mitigating rather than replacing hazardous substances.