Green Ribbon Science Panel

Report-Out for Subcommittee #1

Chemical Identification and Prioritization

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NOTE: In general, the notes set forth in this report-out are presented in the sequence of the subcommittee's discussions rather than strictly by topic. Repeated comments that applied to multiple topics are generally only presented once in these notes.

Question 1A. SHOULD THERE BE MULTIPLE CHEMICAL LISTS?

(i) Should there be a single chemicals list (e.g. COC) or two hierarchical chemicals lists (e.g., COC and PC)?

One or Two Chemical Lists Comments:

- Two lists
  - Develop a short list as a smaller subset of a large list that is the result of prioritization.
  - Second smaller list would include the chemicals that will be acted on
  - Allows for continuous chemical listing updates
  - Includes a process for new chemical nominations in the lists; update the list of chemicals in line with authoritative body source lists.
  - Larger list would provide notice for businesses to plan.
- One list
  - Develop one list from universally accepted authoritative bodies
  - Use a process to "list" chemicals with endpoints that the universally accepted authoritative bodies do not use in compiling their lists; e.g. neurotoxicants, asthmagens
- There are consequences on putting a chemical on a list. It is important to clearly state what the purpose and advantage of having one (less resource intensive) list or two chemical lists.

(ii) If there are two lists, should they be developed concurrently or sequentially?

Two Chemical List Comments:

- Develop the two chemical lists concurrently

(iii) Other ideas?

Other Idea Comments:

- Consider a third process to further narrow down the number of chemicals to proceed with regulatory action (e.g., product identification/prioritization and alternatives analysis) after (1) chemical identification and (2) chemical prioritization.
- Incorporate a process to list chemicals that need an immediate action.
- Use expert elicitation to list or nominate chemicals for listing.

Question 1B. WHAT CRITERIA / PROCESS SHOULD BE USED TO PLACE CHEMICALS ON THE LIST OR LISTS?

(i) Should one or both lists be a compilation of all chemicals listed by other specified authoritative bodies if so which authoritative bodies?

Authoritative Bodies Comments:

- All current authoritative body lists are created with different processes and are evaluated with different quality control/assurances. The listing processes need to be evaluated for robustness (e.g. IRIS, EU CMR list) and the processes need to obtain universal agreement for these authoritative bodies and other "priority" lists (e.g., REACH).
- Important to capture hazard traits of high concern (e.g., neurotoxicants) that current universally accepted authoritative lists do not consider.
- Consider listing relatively data poor chemicals that are not on authoritative bodies lists but have another "red flag", such as high production volume, new chemical substitute for existing hazard, of structural activity relationships similar to those chemicals listed by authoritative bodies.

(ii) Should one or both lists be a compilation of all chemicals that exhibit one or more specified hazard traits? If so, should this be all of the OEHHA listed hazard traits or a subset thereof (if the latter, which ones)?

Hazard Trait Comments:

- The OEHHA hazard traits should pick up chemicals of emerging concern.
- To avoid regrettable chemical substitutions, a (hazard) data poor chemical that is "of concern" should be considered for listing even if the chemical is not on an authoritative list
- Base the larger list on hazard traits, e.g., CMRs, PBTs, and use a pragmatic approach to develop the shorter chemical list.

(iii) What chemical hazard factors should be used to prioritize chemicals?

Chemical Hazard Factor Comments:

- The CMR authoritative lists do not include potency

(iv) Should exposure potential factors also be used to prioritize chemicals - If so, what factors?

Exposure Comments:

- Specific information is needed to determine exposure; e.g. biomonitoring, indoor air monitoring, dust analysis, exposure scenarios to determine/estimate exposure.
- Include in the chemical prioritization scheme environmental effects; e.g., chemical concentrations in water and air.
- Lists will be more relevant if they include an exposure component; e.g., production volume information can be used as a surrogate for exposure.
- Consumer exposure information will be scarce; expert judgment or expert elicitation may aid in determining exposure settings for industrial and consumer uses. Environment Canada and Health Canada did this in prioritizing the Domestic Substance List.
- Exposure surrogates may be used to estimate exposures. For instance:
  - The prominent uses of the chemical and where it will most likely be found (in products) – coating enhancement, conduction of thermal energy
  - The chemical properties – liquid, solid, shelf life
  - The chemical concentration in the product
  - Frequency of chemical exposure from the product (frequent, infrequent)
  - The chemical function in the product
- DTSC will have to obtain from chemical and product manufacturers the information necessary for prioritizing chemicals based on exposure potential (e.g., the factors listed as “exposure surrogates” above: chemical ingredients and concentration in product, use, function in product, sales volume)
- Exposure estimates should include the rationale used for decision making, including the use of expert judgment
- Biomonitoring provides a direct indication of human exposure; chemicals can then be prioritized by considering hazard. Do not equate biomonitoring with hazard.
- However, biomonitoring data are limited to fewer than 300 chemicals (and many fewer if combustion byproducts are excluded). Biomonitoring studies should be used to populate a list of chemicals of concern, but should not serve as a limiting factor
- Account for continual/chronic exposure to the chemical (e.g., BPA)
- Exposure potential evaluation should align with the product prioritization process.
  - Cumulative exposure: develop a list based on consumer product sales volume (i.e., exposure). Where chemicals occur in combination, assume that hazard factors are additive.

(v) If there are two chemicals lists, what chemical hazard factors and what (if any) exposure potential factors should be used for each list?

Chemical Hazard Exposure Comments:

- Physical state of chemicals has bearing on (route of) exposure – dermal, inhalation, ingestion; e.g., liquid or vapor pressure, exposure to solvents even if in moderate concentrations in the product.
- For priority purposes, first consider chemical hazard data, which are more readily available and then exposure.

(vi) In assessing a chemical's threat of adverse impact associated with each identified prioritization factor:

- Should there be a threshold established for each factor – if so, how should the thresholds be determined?

Threshold Factor Comments:

- The process should be risk based.
- A numerical threshold does not have to apply to all chemicals; e.g., PBTs, CMRs.
- Select the hazard criteria and use the Globally Harmonized System of Chemical Classification and Labeling (GHS) as a reasonable start for hazard thresholds
- GHS is objective and decisions can be made based on GHS.
- GHS is a good basis and is used in other regulations and regions; using GHS may help in harmonizing with different regulations in different regions.
- GHS distinguishes different categories of mutagens
- OEHHA's hazard traits provide another objective method to determine thresholds when evaluating evidence; e.g., strong evidence – high priority, suggestive evidence – medium priority
- Use GHS and OEHHA hazard traits with criteria to evaluate "strong evidence"
- A ranking system with numerical weighting can be limiting; e.g., a chemical may be left out because data do not exist, although the chemical is a known problem.
- A threshold system is necessary to narrow the list of chemicals to those of highest concern.
- Do not consider thresholds or priority setting in developing the larger chemical list.
- Using thresholds will focus the state's resources
- It is not clear how setting a threshold for each hazard and then aggregating all the thresholds for each individual hazard will work for prioritizing chemicals.
- Using the term "threshold" is misleading; consider classification system with chemical potency built into the classification system
- GHS may not be compatible with the de minimis subcommittee

- Should the prioritization evaluation be based on the chemicals' individual threat of adverse impact, or the chemical's contribution to cumulative adverse impacts --if the latter, how should this be evaluated?

Cumulative Impacts Comments:

- Chemical potency - the chemical hazard and its endpoint (i.e., adverse impact) is important to prioritization.
- Use the strength of scientific evidence to determine the validity of chemical potency; e.g., a chemical may be prioritized higher than a carcinogen if there are many serious adverse impacts, including environmental impacts, e.g., global warming.
- To evaluate cumulative impacts use the number of hazard traits exhibited by a chemical – the more hazards, the higher priority.
- Cumulative effects and priority should include consideration of potency of, and exposure to, the chemical in the consumer product.
- Cumulative impacts could be evaluated in the same way that cumulative risk assessments with multiple chemicals are now evaluated.
- Use expert judgment (additive, synergistic, etc.) to evaluate cumulative impacts for a family of chemicals with a common mode of action or for chemical mixtures, e.g., gasoline.
- Cumulative impact considerations should include evaluating whether one chemical is in many products, or whether a "chemical cocktail" combination with the same or different endpoints is in one product. These chemical scenarios should be evaluated with chemical potency information and strength of evidence to determine priority.

(vii) Should one or both lists be developed using a ranking formula applied to the identified prioritization factors? If so:

- How should the ranking formula be designed
- Should the factors be weighted? If so, how should the weights be determined?
- Should numerical values (eg 1 to 10) or high-medium-low be used to score each chemical of each factor, and to assign an overall score? How should the scores be determined?

Ranking Formula Comments:

- Look at work already done on ranking chemicals:
  - Canadian and Washington processes,
  - nanomaterials ranking system
  - elicit experts to rank chemicals
  - EPA's Design for Environment (DfE) Program has a ranking system.
- OSHA is incorporating the GHS (although for a different purpose - labeling / hazard communication) into its programs. GHS provides a good starting place and good ranking system for chronic hazards.
- The European Union has a scheme for addressing mixtures
- Keep the ranking processes as simple as possible – don't be process laden.

(viii) Should one or both lists also include known bad actors? If so:

- What are these and/or how should they be determined?
- Should these include chemicals that present end of life concerns or cost concerns?
- Should these include chemicals consider likely to present exposures to sensitive subpopulations?

"Known Bad Actors" Comments:

- Define criteria for "known bad actors". This term may lead to listing chemicals for the wrong reasons and not meet objective criteria adopted in regulations.
- Use an open evaluation process to identify chemicals that are "known bad actors".
- Examples include: chlorinated hydrocarbon solvents, perchloroethylene, methyl chloride – some uses are already targeted.
- There is a growing database for PBDEs. Californians may have higher exposures than the rest of the nation.
- Phthalates have biomonitoring evidence.
- Lead.
- Chemicals with products that have alternatives already developed.
- Use the lists of chemicals that have gone through rigorous process; e.g., EU CMRs, PBTs.

(ix) Other ideas?

Comments:

- Don't screen things out based on resource limitations

Question 1C. **SHOULD THE CHEMICALS LISTS(S) BE LIMITED TO SPECIFIED CHEMICALS OR CHEMICAL CATEGORIES DURING EARLY IMPLEMENTATION YEARS? SHOULD A STAGED IMPLEMENTATION APPROACH BE USED?**

(i) Should there be a scope limitation, or not?

Scope Limitation Comments:

- Scope limitation depends on DTSC; e.g., addressing bad actors first
- Concern was expressed that a chemical or product list in regulations will not be complete or addresses the "right" chemicals or products.

(ii) If there are two chemicals lists, should the scope limitation apply to one or both lists?

Chemical List(s) Scope Limitation Comments:

- Have a larger list and a targeted list. Early implementation years[complete this thought]. Large list – serves to notice businesses of chemicals that may be targeted as priority chemicals. Smaller list – may actually drive substitutions with alternatives for the product within a reasonable time frame.
- The larger the list is, the less social impact it will have.
- Too large a list in the early stages of implementation undercuts how much the agency is able to accomplish.

(iii) What criteria should be used for the scope limitation?

- Hazard traits – which ones?
- Presence on other authoritative bodies lists - which ones?
- Use in specified types of products – which ones?
- End of life management and cost concerns – which ones (e.g, MSW landfill disposal bans, chemicals showing up in state and local waste streams)?

Scope Limitation Criteria Comments:

- Use as a starting point,the REACH criteria to classify substances of very high concern; e.g., CMRs that are category 1 and 2; PBTs, vPvB, use of scientific evidence that there is high probability of impact to humans and environment.
- If resources are limited, it makes sense to use an authoritative list to start; developing chemical list(s) from scratch will set the program back months or years.
- Include in the scope limitation criteria chemicals that are "doable"—those that are likely to be easier to act on.

Other ideas?

Implementation Comments:

- Prioritization process should be "staged." List needs to be manageable by prioritizing the larger list to create the smaller list.
- Implement the prioritization process with short term and long term goals. Start with a chemical list from authoritative bodies and move into product prioritization. Use this initial time to develop, learn, and gain experience. Ideally, at the same time develop procedures for identifying and prioritizing chemical not on an authoritative body list. Overall, this is an iterative learning process.
- Identify a small set of chemicals in the regulations and move forward.

Other Comments:

- Use market mechanisms and opportunities to satisfy the principles of green chemistry.
- Concern is expressed with the scenario whereby DTSC establishes a large chemical list based on authoritative bodies and proceeds to prioritize the chemicals. If there are resources limitations and the only accomplishment after many months is the generation of a large list, it appears that there hasn't been anything done. If, with limited resources DTSC is only able to act on 2 or 3 chemicals, then there should be an "intermediary" chemicals list.
- If the chemical list is too large compared to the chemicals being acted upon, there may be little influence on business behavior changes.