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Chemical Identification & Prioritization
Responses to GRSP Subcommittee 1 Questions

Question #1A: Should there be multiple chemical lists?

(i) **Should there be a single chemicals list or two hierarchical chemicals lists (e.g. "Chemicals of Concern" and "Priority Chemicals")?**

There should be two lists: (1) Chemicals of Concern and (2) Priority Chemicals of Concern. This is consistent with and responsive to the department's mandate to "establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered a chemical of concern…"

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

The two lists should be developed concurrently. The Chemicals of Concern (COC) list should be developed first using defined, evidence-based, and transparent scientific criteria. Using a subset of these criteria and additional criteria, the COC list should be prioritized to a smaller list of Priority Chemicals of Concern (PCOC). Having both lists available at the same time should facilitate regulatory response since it will allow responsible entities to determine whether their consumer products are likely to be subject to the regulation.

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?**

Both lists should be based on specific, evidence-based hazard traits as defined and described in the Green Chemistry Hazard Traits Proposed Regulation (December 12, 2010). Chemicals listed only by organizations that meet the definition of "Authoritative Organization" in the proposed Green Chemistry Hazard Traits should be identified as COCs and PCOCs.

(ii) **Should one or both of the 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)?**

As indicated above, the identification of COCs should be based on hazard traits as defined and described by OEHHA in the proposed Hazard Traits regulation. The criteria used to define what constitutes evidence of the hazard traits is transparent and can help ensure consistency in listing or compiling COCs. The Priority COCs should be a subset of the COC list, so will be based on some of the same hazard traits.

In the initial implementation phase, the following subset of the OEHHA-listed hazard traits should be used to develop the COC and PCOC lists:

1. Carcinogenicity (substances meeting the strong evidence criteria)
2. Developmental Toxicity (substances meeting the strong evidence criteria)
3. Reproductive Toxicity (substances meeting the strong evidence criteria)
4. Endocrine Toxicity (substances meeting the strong evidence criteria)
5. Epigenetic Toxicity (substances meeting the strong evidence criteria)

6. Genotoxicity (substances meeting the criteria for being classified as Category 1 and Category 2 mutagens under the United Nation's Globally Harmonized System for Classification and Labeling Chemicals)
7. Dermatotoxicity (Allergic Sensitization) (substances meeting the strong evidence criteria)
8. Neurotoxicity (Human data) (substances meeting the strong evidence criteria)
9. Respiratory Toxicity (Asthma) (substances meeting the strong evidence criteria)
10. Bioaccumulation
11. Environmental Persistence
12. Global Warming Potential

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

Of the hazards traits enumerated in (ii) above, higher priority hazard factors include those with endpoints that pertain to sensitive subpopulations, those with endpoints that are severe and delayed, those for which there is evidence of widespread exposure to substances that have the hazard trait, and hazard traits for which there is no or a low threshold for toxicity:

1. Carcinogenicity. Depending on other the potential for exposure, transplacental carcinogens should have a higher priority within this hazard trait category.
2. Developmental Toxicity
3. Reproductive Toxicity
4. Endocrine Toxicity
5. Epigenetic Toxicity
6. Genotoxicity (as defined in #6 under (ii).
7. Bioaccumulation
8. Environmental Persistence

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

Yes, exposure potential factors also should be used to prioritize chemical since the goal is to protect public health and the environment from adverse effects caused by chemicals of concern in consumer products. The potential for adverse effects will be determined by inherent toxicity plus exposure.

Exposure potential factors that should be used to prioritize chemicals include:

1. Magnitude of the potential exposure. Is the COC present in many different consumer products or consumer products that are widely used (based on sales volume of products, or other quantitative or qualitative information). Are the COC-containing products used in places or situations that can lead to exposure of large numbers of people either directly, or through contamination of environmental media?
2. Is exposure to the COC in the consumer product likely? Is it present in the consumer product(s) in a form that can enter the body or contaminate the environment? Is the physical form (liquid, dust, fiber, etc.) of the COC in the product compatible with the exposure route on which the toxicity identification or hazard profile is based? If the COC is a liquid, is it volatile? Is it packaged as an aerosol? In other words, is it likely that exposure to the COC in the product via inhalation, skin absorption, etc., or management of the product at end of life could lead to adverse effects?
3. Is there evidence of widespread exposure (such as biomonitoring data) to substances that meet the strong evidence criteria of the prioritized hazard traits in (iii) above? In other

words, is the chemical or substance present in biological media and does it have a prioritized hazard trait?

4. Severity of the potential exposure. Is the COC in products that can lead to exposure of sensitive subpopulations? Will the concentration of the COC in the product cause adverse effects based on its toxicological profile? Is the product containing the COC used in places or in situations where large numbers of sensitive populations are likely to be exposed (hospitals, schools, etc. daycare centers, senior centers)? Can use of the consumer product by businesses and others lead to contamination of environmental media and exposure to large numbers of people or sensitive subpopulations? Is it a consumer product that contains a developmental toxicant potentially used by a large number of pregnant women for which timing of exposure is an important consideration in addition to the concentration of the COC? Is the COC-containing consumer product used in households, or other indoor environments? Is it used frequently?

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

The chemical hazard traits under (iii) and the exposure potential factors listed in (iv) should be used to develop the Priority Chemicals of Concern list, only. The Chemicals of Concern list should be developed in the initial implementation phase using the evidence-based hazard traits listed under (ii) described above.

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

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

For the prioritized chemical hazard traits or factors (see iii above) the threshold for each factor should be based on the strength of the scientific evidence as described in the Proposed Green Chemistry Hazard Traits Regulation. The strong evidence criteria should be used in assessing a chemical's threat of adverse impacts. For the exposure potential factors such as those in (iv) above that are not addressed in the proposed Hazard Traits regulation, the rationale or basis for using the factors will have to be clearly described by the Department when the list of Priority Chemicals of Concern is published and posted for public review and comment.

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

The prioritization should be based first on the chemical's individual threat of adverse impact and then on the cumulative adverse impact. A chemical should be prioritized based on strong evidence of a prioritized hazard trait. If the same chemical also meets the criteria for strong evidence for another prioritized hazard such as bioaccumulation or persistence, or meets other prioritized exposure potential criteria such as those described in (iv), then the chemical's contribution to cumulative adverse impacts should be considered in the prioritization evaluation.

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

Neither list should be developed using a ranking formula applied to the identified prioritization factors. A ranking formula would not be flexible enough to encompass the complexity of the diverse chemical hazard traits and exposure potential hazard traits that must be considered in developing the lists. The lack of precise data on the volume and types of COC-containing consumer products used in the state and by whom, also poses a problem with regard to applying a ranking formula. Given this complexity, the department should describe the types of prioritization factors used and the rationales for adding chemicals to the list of Priority Chemicals when the draft list is published and posted for public review and comment.

(viii) **Should one or both lists also include "known bad actors"?**

If "known bad actors" means chemicals for which there is strong evidence of potential for public health harm, harm to sensitive subpopulations, and/or potential for environmental harm, these chemicals should be on the Priority COC list. Usually, these are chemicals that have been identified for public health action or intervention by government agencies based on other mandates.

λ **What are these and/or how should they be determined?**

Some of these chemicals include lead, mercury, chlorinated hydrocarbon solvents (e.g., perchloroethylene, trichloroethylene, and methylene chloride), formaldehyde, dibutyl phthalate, brominated flame retardants, and bisphenol A.

They can be determined by surveying other governmental programs whose mandates include identifying and evaluating chemical hazards to protect the public and the environment. The CA Environmental Contaminant Biomonitoring Program, Cal/EPA OEHHA, and the CA Department of Public are examples.

λ **Should these include chemicals considered likely to present exposures to sensitive populations?**

Yes. These types of chemicals, which include lead, dibutyl phthalate, brominated flame retardants, and bisphenol A pose health risks to children and the developing fetus.

(ix) **Other ideas?**

In identifying chemicals for listing, the department should pay particular attention to chemicals in consumer products that are marketed to California as being compliant with AQMD VOC regulations or US EPA regulations that prevent ozone depletion. Many of these drop-in substitutes are safer for the environment, but toxic. Examples include N-methylpyrrolidone (NMP) and 1-Bromopropane (1-BP). NMP is a solvent that is used to remove paint and grafitti. NMP is a developmental toxicant that replaced methylene chloride, a carcinogen. 1-BP is a solvent that is used to degrease and in drycleaning. It is a developmental toxicant, a male and female reproductive toxicant, a neurotoxicant, and

was positive in a recent NTP cancer bioassay. I-BP replaced trichloroethane, an ozone depleter.

Question #1C: Should the chemical list(s) be limited to specificd chemicals or chemical categories during the early implementation years.

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

Yes, the scope should be limited in the early implementation years to gain experience with this complex regulatory effort and based on limited resources.

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

The scope limitation should apply only to the Priority Chemicals of Concern list.

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

- **Hazard traits---which ones?**

  See information under (iii) and (iv).

- **Presence on other authoritative bodies' lists---which ones**

  See information under (i).

- **Use in specified types of products --- which ones?**

  See #4 under (iv)

- **End-of-life management and cost concerns---which ones (e.g., MSW landfill disposal bans, chemicals showing up in state and local waste streams)?**

  Professional use of consumer products sold in hardware stores as pure chemicals or in high concentrations are of particular concern with regard to potential disposal concerns.

- **Other ideas?**

  Consult other governmental programs for their suggestions.