



Green Ribbon Science Panel

November 13, 2015



Department of Toxic Substances Control



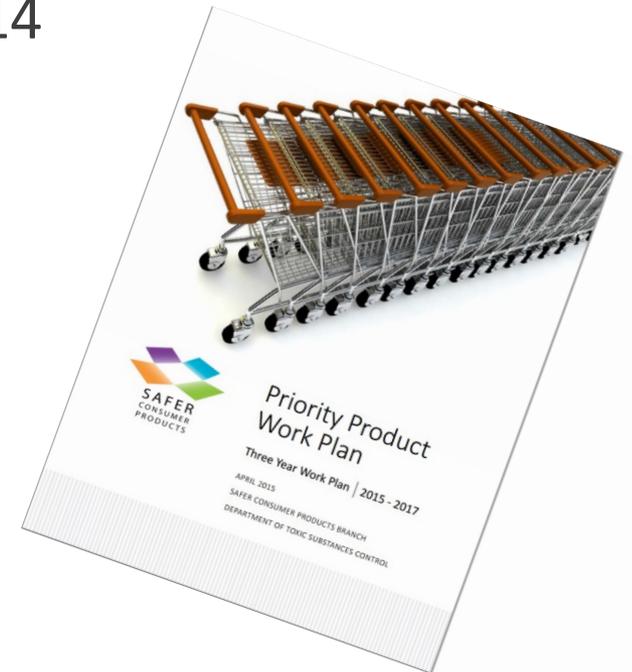
Cal/EPA

CPET Lessons Learned and Process Improvements



CPET Process and Lessons Learned

- First round
 - Product scoping: 2013 – 2014
 - Proposed PPs announced: March, 2014
- Priority Products Work Plan
 - April 2015
 - Five policy priorities
 - Seven product categories
 - *Chemical examples for each*



CPET Process and Lessons Learned

Successes

- Initial profile template
- Cal/EPA Board, Department, and Office (BDO) outreach and research suggestions
- Identified and explained the basis for three priority products
 - *Lots of stakeholder engagement and robust discussion*
 - *New data from industry helped us refine scope*



CPET Process and Lessons Learned

Challenges

- Building a new process from the ground up
- Scoping PPs without final regulations or final list of chemicals
- Finding data – use, market, and exposure
- Lack of a comprehensive set of tools and templates



CPET Process and Lessons Learned

Highlights of “Lessons learned” discussions:

- Need to formalize process and team assignments; include regular briefings for decision-makers
- Need for reviewer standards, templates, style guidance
- More interactions/outreach to other agencies and industry
- Strengthen market research expertise



CPET Process and Lessons Learned

Implementing the 2015 – 2017 Priority Product Work Plan

- Processes to ensure:
 - *Consistent and systematic evaluation of products and chemical data*
 - *Thorough consideration of issues required by regulations*
 - *Record of data we identify and consider, as well as data gaps*



Updated CPET Process

- Six-step process
 - Briefings and decision points after each
- Phase 1: Chemical scoping
- Phase 2: Product Category narrowing
- Phase 3: Public engagement
- ...



CPET Process and Lessons Learned

New templates and tools

- Guidance/instructions (e.g., instructions for scoping teams)
- Reference tools (e.g., Initial Data Sources for specific Policy Priorities)
- Tools for recording and summarizing findings



Implementing the Work Plan

Chemical scoping

- Product categories from the Work Plan assigned to small scoping teams
 - *Goal: diverse experience and expertise*
- Each team is asked to identify key chemicals with potential impacts related to the Work Plan policy priorities
 - *Members free to use whatever approach makes sense to them (consistent with earlier GRSP advice)*



Implementing the Work Plan

Scoping teams

- Assigned to Work Plan categories
 - Goal: diverse experience and expertise
- First task: identify key chemicals with potential impacts related to policy priorities
 - Members free to use whatever approach makes sense to them (consistent with earlier GRSP advice)



Chemical Scoping: Early Results

- Scoping teams using diverse approaches
- Teams independently arrived at similar recommendations
- Several dozen Candidate Chemicals evaluated



Ongoing Challenges

- Limitations of our CC list
- Time and resource constraints
 - Breadth of expertise needed to thoroughly evaluate diverse chemicals and product categories
- Data gaps for:
 - Hazard trait data
 - Product ingredient data
- Evaluating chronic, low-dose exposure to chemicals from products



GRSP Discussion Questions on CPET Process

1. Do you believe the tools we have described will meet the objectives for which they were developed?
2. Can you suggest tools or approaches for addressing the challenges – especially for data gaps for hazard traits, limitations of the CC list, and product ingredient data?
3. How can the GRSP facilitate research in areas of expertise that DTSC lacks?

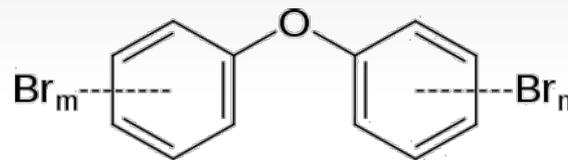


Use of Structural and Functional Chemical Taxonomies to Evaluate Chemicals in Products



Approaches to Grouping Chemicals

- Based on structural features
- Based on their function or functions in products
- Other:
 - By hazard trait
 - By exposure potential
- Examples in the discussion document



Chemical Taxonomies in the Priority Product Work Plan

- Work Plan identifies both structural and functional groupings
 - Azo and benzidine dyes
 - Diisocyanates
 - Fragrances
- Has already led to stakeholders discussion
 - Work Plan goal to facilitate discussion with industry and other stakeholders



Value of Groups in Evaluating Chemicals, Products, and Alternatives

- Different approaches can be useful for:
 - Chemical screening
 - Identifying chemical/product combinations
 - Assessing alternatives
- Blurry line between structural and functional taxonomies
 - Members of a structural class often have functionally similarities and vice versa



Structural Groupings: Benefits

- Useful when a structural feature shared by members of a group is related to a hazard trait
 - Allows DTSC to learn at a more general level without specifying a specific chemical or product
- Some authoritative body lists group structurally-related chemicals



Structural Groupings: Challenges

- Hazard traits may differ significantly between members of a structurally-related class
 - Absent specific data, extrapolating hazard traits has pitfalls
- Not all members are necessarily on Candidate Chemicals List



Chemical Groupings Based on Function

Can be further divided into 3 conceptual levels*

- “Chemical function” level
 - *“Drop-in” replacement chemicals*
- “End use function” level
 - *Alternate ways to achieve the same function as a chemical)*
- “Function as service” level
 - *Alternate ways to achieve a purpose without the function served by a chemical*

* *Advancing Safer Alternatives Through Functional Substitution*

Joel A. Tickner, Jessica N. Schifano, Ann Blake, Catherine Rudisill, and Martin J. Mulvihill

Environmental Science & Technology **2015** 49 (2), 742-749

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Chemical Groupings Based on Function

Benefits when identifying potential priority products

- Chemicals with divergent physicochemical properties and hazard traits may serve the same function in products
 - May become replacements or alternatives
- Important when evaluating potential PPs:
 - What hazard traits do different members exhibit?
 - Which are Candidate Chemicals?



Chemical Groupings Based on Function

Benefits in Alternatives Analysis

- Encourages decision-makers to look beyond structurally similar substitutes (may avoid regrettable substitutions)
- Can help practitioners address data gaps during the screening and evaluation phase
 - *“Read-across” techniques*
 - *Trend analyses*
 - *QSAR models*



Chemical Groupings Based on Function

- Challenges
 - Functional categories often overlap with structural categories
 - Candidate Chemicals list may not encompass all members of a group that have hazard traits
 - Chemicals often serve more than one function and may fall into multiple categories
- Group members may have a wide range of hazard traits



GRSP Discussion Questions on Chemical Taxonomies

1. In implementing the Safer Consumer Products Regulations:
 - When is using a structural class approach most appropriate?
 - When is a functional use class appropriate?
2. Relevant examples?



GRSP Discussion Questions on Chemical Taxonomies

3. How do can structural and functional chemical taxonomies complement, each other?
 - What could the functional use perspective add to conclusions drawn using a structural approach?
 - What if conclusions drawn from structural groupings conflict with those drawn from functional groupings?
4. Can you suggest useful tools for efficiently screening members of complex classes?



GRSP Discussion Questions on Chemical Taxonomies

5. What precautions would the panel give staff about working within a given chemical class framework?
6. Are there other strengths and limitations of using structural and functional use groupings?
7. Are there other chemical taxonomies that may be helpful in DTSC's selection of priority products or evaluation of alternatives?



GRSP Discussion Questions on Chemical Taxonomies

8. What uncertainties should be considered when using structural groups to address data gaps? How should these uncertainties inform:
- A responsible entity's decisions?
 - DTSC's decisions?
9. Do you have experience, or resources for, using a structurally-related chemical groups in alternatives assessment?
- What are the strengths and limitations for this approach?



Questions?

