DTSC Green Ribbon Science Panel
November 14 - 15, 2019
Background Document

This document provides background on topics to be discussed at the November 2019 meeting of the Department of Toxic Substance Control's Green Ribbon Science Panel (GRSP). Some topics have additional supplemental documents that will also be made available. The topics outlined below are focused on supporting the implementation of the Safer Consumer Products (SCP) regulations.

Topic 1. Prioritization Retrospective and Springboard into the Future

Topic 1.1 - Prioritization Retrospective

Topic Summary

As SCP concludes its sixth year of listing Priority Products, it is an appropriate time to reflect on our prioritization process, provide insight into our process, and to examine potential areas for growth. The goals of this Retrospective are also supported by the 2018 Public Health Institute report; "DTSC [SCP] should evaluate the scientific and procedural foundation of its prioritization process to ensure that it is as efficient as possible and that the prioritization strategy is clearly articulated and appropriately transparent." (PHI Report, 2018).

This discussion will be divided into two parts – Prioritization Retrospective and Springboard into the Future. The Retrospective will provide a transparent view into the scientific processes of SCP's prioritization efforts and will highlight the decision-making processes and policies that underlie the selection of Priority Products. The discussion will also focus on the improvements made to the process based on lessons learned. The theme of improvements in the process will be picked up in the afternoon with "The Springboard into the Future" which will focus specifically on PP Profiles, the 2021-2024 Work Plan, and approaches to PP selection.

To prime the discussion on the Retrospective, André Algazi, Supervisor of CPET, will provide insight into the Prioritization Process. A more thorough discussion can be found in the *Safer Consumer Products Program – Six Year Prioritization Retrospective* (Supporting document 1).

Questions to Panel

1. Does GRSP have recommendations to speed up or improve the transparency of our process beyond the process improvement that the DTSC has already undertaken?

2. While the prioritization process has evolved over the course of the Program, the fundamental, non-formulaic approach remains the same. What are the advantages of

this approach in fulfilling SCP's mission? What are the disadvantages and what approaches could be used to mitigate these disadvantages?

3. From PHI, "DTSC should evaluate the scientific and procedural foundation of its prioritization process to ensure that it is as efficient as possible and that the prioritization strategy is clearly articulated and appropriately transparent." Has this retrospective presentation and background paper satisfied this recommendation from PHI? Is there further information needed to help stakeholders understand our process and pace?

4. To date, SCP's stakeholder engagement efforts have centered around public workshops and comment periods, which are time consuming to implement and have been variably effective. While targeted stakeholder outreach may, in some cases, be more effective, it lacks the transparency of the public workshops. Are there other ways that SCP could solicit information while still retaining transparency in our prioritization process? SCP recently facilitated small-table discussions at a workshop; the approach elicited more comments and received positive feedback. Are there additional approaches that would make public workshops and comment periods more effective?

5. There are aspects of the prioritization process that could be achieved by leveraging external resources, including environment-specific chemical prioritization (i.e., aquatic), freeing up DTSC resources and potentially expediting the process. What aspects of the process could be achieved outside of DTSC and how can SCP best leverage these external resources?

6. Should SCP publicize our projects earlier in the scoping phase even though we may not have sufficient information to understand whether it will be a good candidate for a Priority Product? How do we strike the right balance between early stakeholder involvement and the known consequences of daylighting our work, including uninformed substitution or market repercussions?

7. SCP solicits ideas for product-chemical combinations from stakeholders – including NGOs, academics, other BDOs, as well as what staff learn from scientific journals and conferences. What approaches would the Panel recommend to quickly weigh the advantages of these suggestions before investing further time in scoping efforts? Should SCP prioritize particular hazard traits, such as persistence, for continued work?

8. Several recent hires have expertise in data science and have helped SCP mine and aggregate data from disparate sources to identify chemicals or product-chemical combinations for further research. What additional methods or approaches should SCP be using to collect and/or sift through suggested product-chemical combinations to identify those for further scoping?

Key Documents

1.1.1 - Safer Consumer Products Program – Six Year Prioritization Retrospective

Supporting Documents

1.1.2 - Prioritized PP List from 2013
1.1.3 - PP timeline
1.1.4 - Scoping Plan template
1.1.5 - Scoping Report Template_Phase 1
1.1.6 - Chemical and Product Data Sources (*best to view, not print*)
1.1.7 - QuickStart Guide
1.1.8 - PM Roadmap template

Topic 1.2. - How much information should SCP put into a profile?

Topic summary

The SCP Regulations require the Program to make the case for 1) potential exposure to a Candidate Chemical, and 2) the potential for the exposure to cause or contribute to significant or widespread adverse impacts. The potential exposure and the associated adverse impacts are documented in Priority Product Profiles, which provide the scientific basis for the Priority Product Rulemaking. The audiences of these profiles include the public, Responsible Entities, NGOs, peer reviewers, the Office of Administrative Law, other CalEPA boards and departments, and executive management.

Since the initiation of the SCP program, SCP has released seven Priority Product profiles, and a few more are under development. The content of these profiles has evolved in the breadth and depth of scientific details.

Over time, the Program has been tackling more complex questions (e.g., PFAS in carpets and rugs). As a result, the profiles have added more information to try to better address the complexity of more recent proposed Priority Products and provide a more comprehensive document to serve as the basis for our decision. The profiles are shifting from documenting the minimum requirements in the SCP regulations to more comprehensive science assessment documents. For example, the Profile for PFAS in Carpets and Rugs was 137 pages and included more than 600 references; and detailed exposure pathways and conceptual models were presented.

On the one hand, a comprehensive and solid science document might facilitate science communication and decision making; on the other hand, these profiles require a tremendous investment of time by staff and increases the time needed to develop more complex profiles – slowing the pace of work of the program. DTSC would like to strike the right balance between writing scientifically-sound, legally defensible profiles and efficiently listing PPs.

GRSP Questions

1. Given the nature of a Priority Product Profile, i.e., a scientifically-sound and legally defensible document, where do you think the balance lies between thoroughness and the time required to write a profile?

2. To streamline our efforts, in some cases, SCP has elected to focus on the most relevant hazard traits and exposure pathways, although this has been a source of concern for some stakeholders. To what extent should SCP evaluate and document concerns outside of those most relevant to the basis for the Priority Product listing? For example, if SCP's primary concern for a chemical is aquatic toxicity, should SCP also include information about human toxicological endpoints? Should SCP consider benefits (or negative impacts) of including or not including all relevant information to those who might use our profiles for purposes beyond DTSC's rulemaking process? This may result in manufacturers having more work to do in an Alternatives Analysis. What might be the resulting benefits or challenges?

3. In some instances, chemical hazards have been well documented by other authoritative organizations. To what extent should DTSC rely on these external authoritative assessments (e.g., IARC) versus evaluating and documenting the primary literature behind these assessments? Does this change based on the type of authority providing the assessment?

4. What are the potential problems with relying on a few key papers rather than documenting a more comprehensive review of publications?

5. The PP Profile helps to frame the AA by including discussions of relevant factors and the conceptual model for exposure. Would limiting the scope of the Profile, complicate the AA process? Given the short time frames allowed SCP for AA review, would SCP be more likely to issue Notices for Ongoing Review or be more likely to miss important information that may not be provided by the Responsible Entity?

Topic 1.3. Priority Product Selection – Strategic considerations in PP selection

Topic Summary

To date, DTSC has employed a variety of approaches to Priority Products. Initial products were primarily focused on single product-chemical combinations, while more recent listings have used the class approach, for example, listing PFASs in carpets in rugs. Previous comments from GRSP members have recognized the variable approaches to selecting Priority Products and how they may vary in effectiveness and impact. Two contrasting approaches are highlighted below: working on one chemical (class) across many products or listing multiple problematic chemicals in one specific product potentially resulting in the radical reformulation of the product, rather

than taking a piecemeal approach. These strategies would allow certain efficiencies in the Priority Product prioritization process, such as cultivating a deep knowledge of the chemical(s) or deep knowledge of a specific product.

DTSC has, or is likely to use, some of these approaches depending on how they factor into the strategic considerations, as illuminated in the Prioritization Retrospective. GRSP input on the advantages and disadvantages of these approaches, as well as suggesting other strategies that DTSC may consider in its PP selection process, would be valuable. These two approaches are described in more detail below.

One chemical (class) across multiple products

DTSC dedicates tremendous resources to creating a Priority Product profile. For example, the "PFAS in Carpets and Rugs" profile was a significant undertaking (137 pages and over 600 references). This profile took a class approach and includes information on PFASs that would be relevant to other Priority Products. Applying the original PFAS work to other PPs would potentially use a fraction of SCP's time and resources and would act as a method to fast-track future PP listings. It would send a clear signal of concern about a specific chemical or chemical class but would reduce DTSC's capacity to address other chemicals of concern.

Multiple chemicals within a single product

Another approach would be for SCP to perform an in-depth evaluation on one product-type. Rather than taking an incremental approach and dealing with the problematic ingredients one at a time, SCP could highlight all the chemicals that are problematic in the product and encourage wholesale reformulation. This approach would encourage manufacturers to consider the entirety of a product at one time as opposed to piecemeal reformulation and allow for the safest product available with current technology and chemistry. This approach would also be beneficial to DTSC as it would facilitate a deeper understanding of the product and its chemistry and could minimize the costs to manufacturers that occur after reformulation (re-registration, stability testing, etc.).

GRSP Questions:

1. What are the benefits/risks of SCP taking these approaches to Priority Product selection? How should SCP balance these approaches to have the greatest impact?

2. Are there different approaches that we should consider? If so, what are the strengths and weaknesses of those approaches?

3. More broadly, are there other approaches to harness internal and external efficiencies?
    - How should we consider existing alternatives or alternatives assessments into our Priority Product prioritization process?

4. There are concerns that stakeholders could use the time between proposing and regulating a Priority Product to switch to alternative chemicals to avoid the DTSC regulations. How the manufacturers evaluate the alternatives is unknown and may result in regrettable substitutions. Are there different approaches within the limit of, or complementary to, our Regulations, that would preemptively encourage industry to *safely* reformulate or to better leverage other resources? Examples of this could include voluntary programs (e.g., the California Healthy Nail Salon Recognition Program), awards, incentives, supporting external stakeholder efforts and promoting green chemistry education (e.g., the Greener Solutions class at UC Berkeley), or further efforts to signal concern about functional-use classes before listing the Priority Product.

Topic 1.4. Work Plan Development

Topic summary

A draft of the next Priority Product Work Plan is due next year. SCP's Work Plan adheres to the SCP regulations' requirements and is intended to provide some assurance to manufacturers regarding whether their product might be listed as a Priority Product. It differs from a traditional work plan in that it does not provide scope, timelines, and deliverables; instead it offers a menu of product categories and policy priorities DTSC considers in selecting future PPs.

Stakeholders have expressed interest in a more conventional Work Plan, with prescribed timelines. DTSC would welcome input from the GRSP regarding the advantages and disadvantages of these two styles of Work Plans. Additionally, insight into how DTSC can better use the Work Plan to effectively communicate SCP's future directions, concerns for product categories, and possibly exerting pre-emptive pressure to adopt safer chemistries would be welcomed.

GRSP Questions:

1. What have been the most effective elements in the previous Work Plans and what has not been as effective?
2. What are the advantages and disadvantages of SCP's flexible, discretionary style of Work Plan? How do the pros and cons compare with a more conventional Work Plan?
3. What are the impacts of releasing a Work Plan? Does SCP effectively leverage its authority via the listing of product categories within the Work Plan (i.e., signaling to industry)?
4. Are there alternative Work Plan formats that might be more effective in achieving our goals? Should we consider placing more emphasis on functional uses to more strongly signal our concerns?

Topic 2. Alternatives Analysis Threshold Determination

Topic Summary

The Safer Consumer Products regulations allow DTSC to set an Alternatives Analysis Threshold (AAT) when proposing a Priority Product. Manufacturers whose products contain the Chemical of Concern at concentrations below the AAT must notify DTSC that they sell the product and provide evidence that their product meets the AAT, but do not have to comply with the Alternative Analysis requirements of Article 5 in SCP's regulations.

DTSC can elect to establish an AAT for a specific Priority Product, but in most cases is not required to do so. In the case of an unintentionally added ingredient, an AAT is required but is assumed to be equivalent to the Practical Quantitation Limit (PQL) unless DTSC elects to set an AAT above that value. The PQL must be specified by DTSC and is loosely defined in the SCP regulations as the level at which a contaminant can be reliably measured by most laboratories using routine laboratory procedures.

DTSC has not yet opted to set an AAT for a proposed or adopted Priority Product. However, DTSC has been researching the contaminant 1,4-dioxane in personal care and cleaning products. 1,4-dioxane is a contaminant associated with production of ethoxylated surfactants often used in these products. Despite toxicity concerns, companies have struggled to completely remove 1,4-dioxane from their products. 1,4-dioxane is also analytically challenging, and detection limits are constantly evolving as analytical methodologies improve.

Over the last few months, DTSC has released a background document and AAT discussion proposal to inform our stakeholder engagement efforts to learn more about 1,4-dioxane in personal care and cleaning products. DTSC incorporated input from the April 2019 GRSP meeting AAT topic in crafting these documents. We received feedback on the documents from stakeholders over the course of two summer workshops and a public comment period. This feedback raised several issues for DTSC to consider in setting an AAT and potentially listing a Priority Product containing 1,4-dioxane, outlined below. Additionally, because each Priority Product for which an AAT is needed or required will have its own unique challenges, we want to avoid creating a listing for a 1,4-dioxane Priority Product that sets an unattainable precedent for future Priority Product listings.

<u>Analytical Requirements</u>

Listing 1,4-dioxane as a Chemical of Concern in a Priority Product with an AAT will result in at least some manufacturers having to submit analytical testing data to demonstrate that the concentration of 1,4-dioxane in their product is below the established AAT value. To determine manufacturer compliance, we must establish data quality criteria so that we can effectively evaluate the data we receive. Other regulatory programs generally specify a test method to be

used when setting regulatory thresholds. However, there is no accepted and validated test method for the analysis of 1,4-dioxane in personal care or cleaning products. Moreover, many of the chemicals that DTSC will consider under the scope of the SCP program will similarly not have validated test methods. In the absence of a test method, or in order to provide more flexibility to responsible parties, data quality criteria could be specified to provide guidance to stakeholders as well as lay out the criteria by which the data will be evaluated. The extent of these data quality criteria could vary widely in scope, specificity, and complexity.

DTSC could also allow formulators to report 1,4-dioxane product level concentrations derived from the concentration of 1,4-dioxane in the ingredients used to make the products. This alternative to submitting product level testing data could reduce the burden of analytical testing on formulators by allowing them to calculate the expected 1,4-dioxane concentration in the final product based on 1,4-dioxane concentration data they receive from their suppliers and known dilution of those ingredients into the final product. The table below highlights some preliminary pro and cons around these questions to help inform the discussion.

Consideration	**Pros**	**Cons**
Product Level Data Option 1) Do not specify data quality criteria	• Fastest, least complicated path to regulation • Places initial analytical burden on responsible entities (REs) rather than on SCP	• Industry resistance (prefer a validated test method) • Variable data quality received could make data evaluation very challenging • Enforceability concerns
Product Level Data Option 2) Specify data quality criteria	• Gives REs options for product analysis • Provides transparency for data quality expectations • Strengthens regulatory enforceability • Onus on REs and contract labs to determine methods that meet the criteria	• Industry resistance (prefer a validated test method) • Variable analytical methods could make data evaluation time consuming • Time and resources to research and collaborate with DTSC's Environmental Chemistry Lab to establish reasonable criteria

Product Level Data Option 3) Develop, validate, and set a test method	• No ambiguity in data quality expectations • Significantly reduced DTSC workload during evaluation • Maximum regulatory enforceability	• Limit REs options for product testing • Time and cost to develop and validate a method • Dependence on external labs for collaboration • Sets a high bar for future AATs
Consideration	**Pros**	**Cons**
Ingredient Level Option Also allow product level calculations derived from ingredient level analytical data as an option for reporting (as opposed to accepting only product level analytical data)	• Shifts the burden onto the surfactant manufacturers • Encourages supply chain transparency • Less specialized equipment / cheaper analysis of 1,4-dioxane at the ingredient level (higher concentrations in surfactants could still meet the product-level AAT) • Leverage existing test methods for 1,4-dioxane in ethoxylated surfactants • Provides other options for REs to generate product level data	• Complicates the types of data we receive • May require SCP to specify the ingredient types that must be analyzed for 1,4-dioxane • May need to set data quality criteria at the ingredient level • May underestimate the true product concentration if untested ingredients contain 1,4-dioxane

<u>Product-Specific Considerations</u>

Multiple stakeholders, particularly those from the cleaning industry, raised the issue of concentrated products. These products have numerous environmental benefits, including reduced greenhouse gas emissions during transport and less packaging; however, they are likely to have higher levels of 1,4-dioxane due to their concentrated nature and are therefore less likely to be able to meet the AAT. The California Air Resources Board has dealt with this issue by allowing for dilution calculations:

> "For consumer products for which the label, packaging, or accompanying literature specifically states that the product should be diluted with water or non-VOC solvent prior to use, the limits … shall apply to the product only after the minimum recommended dilution has taken place." (California Air Resources Board's Regulation for Reducing Emissions from Consumer Products, July 2009, Subchapter 8.5, Article 2, 94509(b)(1)).

Stakeholders have recommended that DTSC take a similar approach in any 1,4-dioxane Priority Product listing. This approach would be consistent with other California regulatory programs and would avoid a scenario in which manufacturers stop producing concentrated products just to get below the AAT. However, this approach would make the regulations and notifications process more complicated and might create loopholes if changes in product labeling are used to satisfy an AAT. It could also set an undesirable precedent for future Candidate Chemicals needing an AAT that may behave differently from 1,4-dioxane (e.g., if the chemical is not a contaminant that scales with the product's active ingredient).

Product Listing

Given the large number of manufacturers in the personal care and cleaning product categories and sub-categories, stakeholders are concerned about the amount of information that DTSC will receive in a Priority Product listing of 1,4-dioxane. DTSC must also consider the resources needed to handle a Priority Product that encompasses a large number of responsible entities (REs). There are multiple approaches that DTSC could take in listing a Priority Product containing 1,4-dioxane to focus the scope and reduce the number of REs. One approach is to define the Priority Product as a product that includes a specific ingredient class most likely to contain 1,4-dioxane (example: "1,4-dioxane in laundry detergents containing anionic surfactants", as opposed to "1,4-dioxane in laundry detergent"), while not including other ingredients that might be a lesser source of 1,4-dioxane.

This approach would focus our efforts and resources where the largest impact could be made and could reduce SCP workload by reducing the number of products. However, this approach would require time to understand which chemical classes would make the biggest impact on 1,4-dioxane concentrations in products and how narrowing the scope would affect the number of REs. Additionally, this approach may exclude some products within the larger product category (i.e., laundry detergents) that have 1,4-dioxane concentrations above the AAT.
DTSC welcomes input from the GRSP on the questions below as we work to synthesize feedback from stakeholders and begin the decision-making process on the next steps with 1,4-dioxane.

Questions to Panel

1. Should DTSC move forward with an AAT for a contaminant like 1,4-dioxane absent a validated test method? If not, what role should SCP play in establishing a validated test method?
2. What are the implications of waiting for method validation?
3. If a validated method is needed, how can we incentivize manufacturers and contract labs to work together to validate a method?
4. To what extent should DTSC specify acceptable data quality criteria in reporting? What are the implications of setting data quality criteria (i.e., financial, legal, etc.)?
5. What strategy should SCP use to address concentrated products? What would the pros and cons be of this approach?
6. Should DTSC allow for dilution calculations to prove that they are below the AAT? What are the pros and cons of this approach?
7. Should DTSC consider specific Priority Product listing approaches to narrow the scope of the responsible entities, as outlined above? What are the anticipated pros and cons? In what instances, beyond 1,4-dioxane, should DTCS consider listing approaches to narrow the responsible entities?
8. SCP could consider outlining a progressive AAT, where the threshold starts at a higher number and is gradually lowered over a set time frame (i.e., 5 ppm by 2022, 3 ppm by 2024, 1 ppm by 2026). What are the implications of this approach? In what instances should DTSC consider this approach? How does this approach align with the goals and values of the SCP Program?

Supporting Documents

2.1 – 1,4-Dioxane Background Document

2.2 – 1,4-Dioxane Draft Discussion AAT Proposal

Appendix – Pertinent DTSC AAT Regulations and FSOR excerpts

Topic 3. Green Chemistry R&D Regulatory Response – lightning round brainstorm

Topic Summary

DTSC will have to start determining Regulatory Responses (RR) within a year of the receipt of a compliant Abridged AA. One of the requirements of the Abridged AA is to examine the RR regarding the advancement of green chemistry and engineering. The Regulations provide little guidance to develop this RR.

> "The department may require the manufacturer to initiate research & development project or fund a challenge grant pertinent to the PP that uses green chemistry and/or green engineering principles to do 1 or more of the following: a) design a safer alternative, b) improve the performance of a safer alternative to the PP, c) decrease the

cost of the safer alternative, d) increase market penetration of the safer alternative." §69506.8

This quick brainstorming session on how SCP can effectively use this Regulatory Response to stimulate green chemistry innovation will help SCP to develop a model that can be used for a more robust discussion at the following GRSP meeting. Some considerations to stimulate thinking are below. Note, these questions do not need to be answered at this meeting.

- How should the scientific question and the desired outcome be developed?
- What appropriate financial investment, scientific quality, or solution practicality criteria should SCP use to develop this RR?
- How will DTSC ensure quality of the proposed study (SCP Review, Peer Review, etc…)
- Models to apply in planning for this RR
    - For example, CG3 challenges, R&D-focused Supplementary Environmental Projects, Safermade
- Appropriate levels of R&D investments to make progress on green alternatives
- Means of encouraging collaboration – like the GC3 preservative challenge. Ways to incentivize collaboration in our response.

Questions for GRSP

1. How should SCP determine appropriate parameters for this, both scientifically and financially?
2. What models can SCP follow in developing this RR?
3. How can SCP use this RR to effectively promote Green Chemistry innovation?

Supporting documents

3.1 – Reo,J. 2018. *Green Chemistry and Commerce Council (GC3) and InnoCentive Announce award recipients in the challenge for novel green preservatives*. Globalnewswire.com. Accessed Oct 17, 2019. http://www.globenewswire.com/news-release/2018/08/06/1547416/0/en/The-Green-Chemistry-Commerce-Council-GC3-and-InnoCentive-Announce-Award-Recipients-in-the-Challenge-for-Novel-Green-Preservatives.html

3.2 – USEPA Small Business Innovation Research Program https://www.epa.gov/sites/production/files/2019-10/documents/epa_sbir_trifold_2019.pdf

Appendix – Pertinent DTSC AAT Regulations and FSOR excerpts