

DTSC GREEN RIBBON SCIENCE PANEL

October 30, 2020

Background Document

This document provides a brief background on the topic to be discussed at the October 2020 meeting of the Department of Toxic Substance Control's Green Ribbon Science Panel (GRSP). The topic outlined below is focused on supporting the implementation of the Safer Consumer Products (SCP) regulations.

Data Analysis for Priority Product Selection

Problem Statement:

Large data sets are becoming increasingly available. These data may offer critical insight into making smart Priority Product selections, but they come with a cost. Extracting, cleaning, and harmonizing data from different sources, and conducting and presenting analyses, are becoming proportionally harder. Searching for data beyond what is minimally necessary to make an informed decision can significantly lengthen the Priority Product selection process so we must identify how good is good enough, and balance that with any benefits derived from more extensive research efforts. With SCP's limited resources, it is critical for SCP to optimize our efforts in selecting a Candidate Chemical-Priority Product combination that will have substantial impact.

GRSP Input:

SCP would like GRSP members to provide personal observations on the evolution of data-based decision making from their own work and help us address this overarching question: How can SCP use data to better inform Priority Product selection and prioritization without overburdening the program and lengthening the Priority Product selection process?

SCP Outcome:

SCP will use the input from GRSP to inform how we weigh the potential effort and potential gain of conducting future data analyses as part of our decision-making process.

Topic Summary

We'll frame this discussion around a particularly challenging case study for listing a Priority Product containing the contaminant, 1,4-dioxane. We will discuss SCP's attempts to obtain and analyze various types of data to rank personal care and cleaning products by their possible levels of 1,4-dioxane contamination, potential exposure, and potential adverse impacts. Several complicating factors (see Supplementary Table 1) and the absence of recent, thorough product testing make the specific Priority Product selection difficult.

As part of the SCP regulations, we are required to substantiate the potential for exposure and the potential for significant or widespread adverse impacts, and to give special consideration to sensitive subpopulations. 1,4-Dioxane was initially prioritized because its presence in wastewater creates a unique and costly challenge for wastewater treatment and water reclamation plants, which is considered an adverse impact factor in the SCP regulations. Several datasets were used to demonstrate widespread exposure to 1,4-dioxane in drinking water above the U.S. EPA's health advisory level. The drinking water detection data were then mapped onto the Office of Environmental Health and Hazard Assessment's CalEnviroScreen model that identifies the location of environmental justice communities in the state. This analysis clearly demonstrated a disproportionate impact to sensitive subpopulations. Additionally, we further determined whether potential Priority Product use could be responsible for a large fraction of the 1,4-dioxane found in wastewater. The variability in the amount of contaminant present in a product and lack of sufficient testing data presented challenges to a direct approach to assess exposure factors and adverse impact factors. Instead, we performed a back-of-the-envelope calculation to estimate how much of the 1,4-dioxane present in wastewater could be due to the use of potential Priority Products. Our ongoing collaboration with the U.S. EPA Office of Research and Development will also allow us to refine how population dynamics impact 1,4-dioxane release from consumer products.

Once we had confirmed the potential for exposure and significant or widespread adverse impacts, we needed to select the specific Priority Product. However, data that would help narrow the Priority Product selection were not in an immediately usable format, not of high enough quality to be useful, or not available. The limited data we could find on concentrations of 1,4-dioxane in products and product use scenarios suggested that the amount of 1,4-dioxane entering the wastewater stream could vary widely depending on our selection of a specific Priority Product. 1,4-Dioxane is a contaminant in ethoxylated ingredients and varies in concentration by orders of magnitude based on the ingredient synthesis process and the type of ethoxylated ingredient. Ethoxylated ingredients are ubiquitous in both personal care and cleaning products. Thus, a broad Priority Product selection could cover tens of thousands of products and impact hundreds of Responsible Entities (REs), while the actual number of products with high concentrations of 1,4-dioxane is likely much smaller. An overly broad Priority Product definition could involve many REs that are not a significant part of the problem and overwhelm our program with tens of thousands of notifications, so we needed an approach to narrow the Priority Product definition. In addition, because the candidate chemical is a contaminant, SCP is required to set an Alternatives Analysis Threshold (AAT). Determining which Priority Products were the biggest problem, in conjunction with the down-the-drain estimates allowed us to examine whether an impactful AAT was possible.

To narrow the Priority Product selection, we generated a matrix for product selection decision making (see Supplementary Table 2 and associated data sets in Supplementary Table 3). Specifically, this matrix was used to determine the most impactful Priority Product and consider the impact of further narrowing the Priority Product by defining it based on a subset of ethoxylated ingredients. This narrower definition has the potential to limit the number of REs and Priority Products while simultaneously targeting the products with the most impact on wastewater. Additionally, a narrow definition may still have a broad impact if the ingredient limitation leads to

safer ethoxylated ingredients in general. The technology to manufacture safer ethoxylated ingredients exists but is not practiced widely due to the capital cost of installing extra treatment equipment. If this technology becomes common practice, it could reduce 1,4-dioxane in broad menu of products with 1,4-dioxane challenges.

As shown in the decision-making matrix, laundry detergent will mostly likely have the greatest impact on the concentration of 1,4-dioxane in wastewater; however, there is considerable uncertainty associated with dish detergent. SCP opted to write a broad profile that describes the overall potential for exposure to 1,4-dioxane and widespread adverse impact due to its presence as a contaminant in personal care and cleaning products. Subsequent rulemaking packages will follow to name specific Priority Products within the broader category of personal care and cleaning products. After those rulemakings we may reassess the 1,4-dioxane levels in shampoo and body wash to determine whether our “signaling” and New York State’s law have reduced the amount of the chemical in these products. In principle, our analyses could be refined further with product level testing and data call-in. Unfortunately, there were significant delays in product testing and the CalSAFER modules and procedures for data call-in were still in development. Data call-in and product testing will be discussed in future GRSP meetings. Here, we will focus specifically on the data analysis piece.

Charge Questions to Panel

1. Selecting an impactful Priority Product containing 1,4-dioxane was challenging due to the presence of the contaminant in numerous possible Priority Products, the dearth of recent product testing data, and several other factors. Given these challenges, our regulatory mandate, and limited resources, can you suggest any improvements to the approach we have taken? How can SCP set optimization criteria for future analyses to ensure that we are being good stewards of taxpayers’ money?
2. What have you observed regarding the evolution of data-based decision making? What lessons can SCP learn from your past or current experience?
3. The level of data analysis efforts required for listing a Priority Product varies. Can we develop criteria for recognizing the point of diminishing returns?
4. This analysis involved a single, data rich chemical. How can SCP temper the expectations that the same analysis could be conducted on a large family of chemicals or chemicals with significant data gaps?
5. Sound science needs to be at the core of our multifactor decision-making process. How can we appropriately weigh other practical considerations (i.e. the number of REs, market share, environmental justice) during our assessment process?

Considerations

1. This analysis drew on databases of chemical ingredients, chemicals, and exposure. Are there databases that we missed that might help us streamline this process?
2. How can we make this process clear and transparent to the public?
3. How can we encourage our scientific partners to provide us with more aggregated and prioritized data to streamline the SCP prioritization and Priority Product selection processes? Are there groups that we could collaborate with who might have more resources for this type of data analysis?

Supplementary Tables

Table 1. Complicating factors and data-related challenges

Challenge	Example or explanation
Data are not in a convenient format	<ul style="list-style-type: none"> UCMR3 location data were limited to zip codes rather than census tracts
Data require significant cleaning	<ul style="list-style-type: none"> Mintel database ingredients do not include CAS RN, thus chemistry expertise and other resources were needed to explore the possible impact of limiting the product definition by ingredient type or class
Data are unavailable or insufficient	<ul style="list-style-type: none"> Product testing data are not up to date Existing product data do not sufficiently cover the broad range of possible product concentrations
Data are not useable	<ul style="list-style-type: none"> Water Board monitoring data had variable detection limits above concentrations of concern Ingredient names are generic “anionic surfactant” Product testing had unreasonably high quantitation limit
Multiple data sets with similar data are of variable quality	<ul style="list-style-type: none"> Two drinking water datasets (UCMR3 data and Water Board monitoring data) sampled over different time frames, monitored different locations, and used different methods with differing detection limits. Literature research results for product testing included aggregated data, averaged data, and individual data points. These studies also had different detection limits and testing methodologies.
The Candidate Chemical (CC) is a contaminant in a broad array of chemicals (ethoxylated ingredients) that are ubiquitous in personal care and cleaning products	<ul style="list-style-type: none"> The chemical does not appear on the ingredients list, making it difficult to determine in which products and at what concentration it is present Ethoxylated ingredients are often the active ingredient in these products, vary in composition, and include several classes of compounds
The amount of contaminant present varies by orders of magnitude and is driven by both the type of ethoxylated ingredient and the manufacturing process	<ul style="list-style-type: none"> A product that contains an alcohol ethoxylate may have < 1 ppm 1,4-dioxane, but concentrations may exceed 100 ppm in some products containing AESs. Manufacturing processes are often considered CBI and are thus difficult to track.
If regulated broadly, all players, even those unlikely to have any contaminant present, will have to test and submit notifications	<ul style="list-style-type: none"> Simply dealing with Notifications from 1000’s of REs could gravely tax SCP resources

Table 2. Decision Matrix

Consideration	Possible Priority Product			
	Laundry detergent	Manual dishwashing detergents	Shampoo	Body wash/ bubble bath/ hand wash
Mean 1,4-dioxane concentration in products	4.61 ppm	4.6 ppm	1.66 ppm	2.04 ppm
Maximum 1,4-dioxane concentration in products	14 ppm	7.7 ppm	5.5 ppm	7.6 ppm
Products in dataset (n)	18	5	23	8
% of products in dataset with <1 ppm 1,4-dioxane	33%	0%	39%	50%
Mean contribution to effluent from product use	0.51 ppm	0.15 ppm	0.08 ppm	0.24 ppm
Total number of products	1,759	914	6,612	7,959+
Total number of REs	96	101	288	286+
% of products covered if limited to those with ethoxylated ingredients	80-90%	70-80%	≈70-80%	Unusable data
% of products covered if limited to those with AESs	≈40-50%	≈50-60%	Unusable data	Unusable data
Sales (tons/day)	1,013	253	198	165-335

Table 3. Data Types

Data or data calculation	Supporting data sets	Questions addressed
Potential concentration of 1,4-dioxane in the product	<ul style="list-style-type: none"> • SCP-assembled product database • Lab testing data (pending) 	<ul style="list-style-type: none"> • Is there widespread Exposure? Will an AAT be impactful?
Potential relative product contribution of 1,4-dioxane to the “down-the-drain” pathway	<ul style="list-style-type: none"> • U.S. EPA Exposure Factors Handbook • LACSD WRP capacity and population served 	<ul style="list-style-type: none"> • Is there significant adverse impact to wastewater treatment facilities? • Will an AAT be impactful in addressing the wastewater issue?
Sensitive subpopulation distribution	<ul style="list-style-type: none"> • CalEnviroScreen 3.0 	<ul style="list-style-type: none"> • Are sensitive subpopulations disproportionately affected?
Environmental monitoring datasets	<ul style="list-style-type: none"> • UCMR3 drinking water data, Water Board monitoring data, 	<ul style="list-style-type: none"> • Is there widespread exposure?
Market presence	<ul style="list-style-type: none"> • CARB Consumer Product Database, Mintel 	<ul style="list-style-type: none"> • Is there widespread exposure?
Population potentially affected	<ul style="list-style-type: none"> • US Census data, county level • UCMR3 drinking water data 	<ul style="list-style-type: none"> • Is there widespread exposure?

Abbreviations

AAT	Alternatives Analysis Threshold
AES	Alcohol ethoxysulfate
CAS RN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CC	Candidate Chemical
GRSP	Green Ribbon Science Panel
LACSD	Los Angeles County Sanitation Districts
RE	Responsible Entity
SCP	Safer Consumer Products
UCMR3	Third Unregulated Contaminant Monitoring Rule
U.S. EPA	United States Environmental Protection Agency
WRP	Water Reclamation Plant

Appendix

Relevant sections of the SCP Framework Regulations

§ 69503.2. Product-Chemical Identification and Prioritization Factors.

(a) Key Prioritization Principles. Any product-chemical combination identified and listed as a Priority Product must meet both of the following criteria:

- (1) There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
- (2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

(b) Identification and Prioritization Process. The Department may identify and list as a Priority Product one or more product-chemical combinations that it determines to be of high priority. The Department's decision to identify and list a product-chemical combination as a Priority Product shall be based on an evaluation of the product-chemical combination to determine its associated potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects by considering the factors described in paragraphs (1) and (2) for which information is reasonably available. The Department may additionally, in its discretion, consider paragraph (3).

(1)(A) Adverse Impacts and Exposures. The Department shall begin the product-chemical combination evaluation process by evaluating the potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures during the life cycle of the product. The Department's evaluation of potential adverse impacts and potential exposures shall include consideration of one or more of the factors listed in section 69503.3(a) and one or more of the factors listed in section 69503.3(b). The listing of a product-chemical combination as a Priority Product shall be based on one or more of the factors listed in section 69503.3(a) and one or more of the factors listed in section 69503.3(b), in addition to the other factors specified in this section.

(B) Adverse Waste and End-of-Life Effects. The Department may also consider product uses, or discharges or disposals, in any manner that have the potential to contribute to or cause adverse waste and end-of-life effects associated with the Candidate Chemical(s) in the product.

(C) Availability of Information. The Department shall consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects. In evaluating the quality of the available information, the Department shall consider, as applicable:

1. The level of rigor attendant to the generation of the information, including, when relevant, the use of quality controls;
2. The degree to which the information has been independently reviewed by qualified disinterested parties;
3. The degree to which the information has been independently confirmed, corroborated, or replicated;
4. The credentials and education and experience qualifications of the person(s) who prepared and/or reviewed the information; and
5. The degree to which the information is relevant for the purpose for which it is being considered by the Department.

§ 69503.3. Adverse Impact and Exposure Factors.

(a) Adverse Impacts.

(1) In evaluating a product-chemical combination for possible listing as a Priority Product, the Department shall evaluate the potential for the Candidate Chemical(s) to contribute to or cause adverse impacts, by considering one or more of the following factors for which information is reasonably available:

(A) The Candidate Chemical(s)' hazard trait(s) and/or environmental or toxicological endpoint(s);

(B) The Candidate Chemical(s)' aggregate effects;

(C) The Candidate Chemical(s)' cumulative effects with other chemicals with the same or similar hazard trait(s) and/or environmental or toxicological endpoint(s);

(D) The Candidate Chemical(s)' physicochemical properties;

(E) The Candidate Chemical(s)' environmental fate;

(F) The human populations, and/or aquatic, avian, or terrestrial animal or plant organisms for which the Candidate Chemical(s) has/have the potential to contribute to or cause adverse impacts; and/or

(G) The potential for the Candidate Chemical(s) to degrade, form reaction products, or metabolize into another Candidate Chemical or a chemical that exhibits one or more hazard traits and/or environmental or toxicological endpoints.

(2) The Department shall give special consideration to the potential for the Candidate Chemical(s) in the product to contribute to or cause adverse impacts for:

(A) Sensitive subpopulations;

- (B) Environmentally sensitive habitats;
 - (C) Endangered and threatened species listed by the California Department of Fish and Wildlife; and
 - (D) Environments in California that have been designated as impaired by a California State or federal regulatory agency.
- (3) The Department may also evaluate and consider, based on reliable information, the adverse impacts associated with structurally or mechanistically similar chemicals for which there is a known toxicity profile.

(b) Exposures. In evaluating a product-chemical combination for possible listing as a Priority Product, the Department shall evaluate the potential for public and/or aquatic, avian, or terrestrial animal or plant organism exposure(s) to the Candidate Chemical(s) in the product, by considering one or more of the following factors for which information is reasonably available:

- (1) Market presence of the product, including:
 - (A) Statewide sales by volume;
 - (B) Statewide sales by number of units; and/or
 - (C) Intended product use(s), and types and age groups of targeted customer base(s).
- (2) The occurrence, or potential occurrence, of exposures to the Candidate Chemical(s) in the product.
- (3) The household and workplace presence of the product, and other products containing the same Candidate Chemical(s) that is/are the basis for considering the listing of the product-chemical combination as a Priority Product.
- (4) Potential exposures to the Candidate Chemical(s) in the product during the product's life cycle, considering:
 - (A) Manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices;
 - (B) Whether the product is manufactured or stored in, or transported through, California solely for use outside of California;
 - (C) Whether the product is placed into the stream of commerce in California solely for the manufacture of one or more of the products exempted from the definition of "consumer product" specified in Health and Safety Code section 25251;
 - (D) The following types of uses:
 - 1. Household and recreational use;
 - 2. Sensitive subpopulation potential use of, or exposure to, the product; and/or

3. Workers, customers, clients, and members of the general public who use, or otherwise come in contact with, the product or releases from the product in homes, schools, workplaces, or other locations;
 - (E) Frequency, extent, level, and duration of potential exposure for each use scenario and end-of-life scenario;
 - (F) Containment of the Candidate Chemical(s) within the product, including potential accessibility to the Candidate Chemical(s) during the useful life of the product and the potential for releases of the Candidate Chemical(s) during the useful life and at the end-of-life;
 - (G) Engineering and administrative controls that reduce exposure concerns associated with the product; and/or
 - (H) The potential for the Candidate Chemical(s) or its/their degradation products to be released into, migrate from, or distribute across environmental media, and the potential for the Candidate Chemical(s) or its/their degradation products to accumulate and persist in biological and/or environmental compartments or systems.