

Background Memo: Approaches to Product Category Identification for the 3 Year Priority Products Work Plan

Green Ribbon Science Panel June 25, 2014

Introduction

In October 2014, Department of Toxic Substances Control's (DTSC's) Safer Consumer Products (SCP) Program will publish a work plan to identify product categories from which Priority Products may be selected in the coming three years. This memo provides background information about the product category selection process for the three year work plan. DTSC's Green Ribbon Science Panel (GRSP) will meet on June 25th and will discuss the approach to the three year work plan. This memo provides background for that discussion. It is not a draft of the work plan. Approaches and categories mentioned in this memo are intended to serve as possible examples and will not necessarily be named in the work plan.

Background

DTSC's SCP regulations¹ require the Department to issue a 3-year work plan that includes two elements:

1. A description of "the product categories that the Department will evaluate to identify product-chemical combinations to be added to the Priority Products list during the" subsequent three years, and
2. A "general explanation of the decision to select the identified product categories for evaluation..."

The Product Research Branch intends to hold a public workshop during the week of August 11, 2014.

Considerations in Selecting Product Categories

DTSC may only identify a product as a Priority Product if it falls into one of the categories identified in the work plan.² Therefore it is important that DTSC take care in selecting product categories, balancing the need to have a sufficiently broad pool of products from which to choose and the need to have sufficiently narrow product categories to provide meaningful signals to the market about what products DTSC may select during the work plan cycle. Market signals are important because they may motivate manufacturers, product designers, and formulators to preemptively phase out Candidate Chemicals in products that fall within a work plan category. In selecting product categories, DTSC must be mindful of the SCP regulations' key prioritization factors and the regulatory constraints limiting priority product selection. DTSC understands the importance of identifying a strategic direction in the work plan.

Key Prioritization Factors

The regulations identify the two key prioritization factors:

1. The products have the potential to expose people or the environment to one or more Candidate Chemicals.
2. This exposure has the potential to contribute to or cause significant or widespread adverse impacts.

¹ Chapter 55 of title 22 of the California Code of Regulations.

² However, the SCP regulations allow DTSC to revise the work plan during its 3-year term in two cases: if the Department "is legally required to take action on a particular chemical or product, or both," or in response to a (granted) petition.

Regulatory Constraints

In selecting product categories for the Priority Product Work Plan, DTSC must be mindful of the constraints of the statute and SCP regulations on the types of products it may designate Priority Products with Chemicals of Concern.

- We may not choose products that are excluded from the definition of “consumer product” (e.g., pesticides and prescription drugs).
- We may not choose products that are adequately regulated by another State or federal agency (“... equivalent to or greater than the protection that would potentially be provided if the product were listed as a Priority Product”).
- We may not choose products that do not meet the key prioritization principles (i.e., there is potential exposure to a Chemical of Concern in the Priority Product that causes or contributes to “significant or widespread adverse impacts”)

Our product categories will be selected with an eye to these constraints (understanding that within a category, some products may meet them and others may not).

Approaches to Product Category Screening

The selection of the initial Priority Products announced in March 2014 was based largely on nominations of product-chemical combination by governmental agencies and other interested parties. The number and breadth of nominated product-chemical combinations demonstrates the wealth of possible Priority Products in commerce. In fact, the sheer number of possible combinations of products, chemicals, and exposure scenarios make ranking and scoring systems impracticable for identifying and prioritizing products or product categories. DTSC will make policy decisions to prioritize among the possibilities. Science informs policy and sound science will provide a foundation for selections. Additionally, policy decisions will rely on the provisions in the regulations for evaluating adverse impacts, exposures, or end-of-life effects, as well as the availability of information, other regulatory programs’ scope, and safer alternatives. Practical considerations, efficiency, and transparency will also inform departmental policy priorities.

At the April 2014 GRSP meeting, panelists encouraged DTSC to cast a wider net in identifying potential Priority Products, rather than relying exclusively on nominations. To that end, the Department has identified a number of possible approaches, described below, to use to screen potential product categories for inclusion in the Priority Products Work Plan. Each approach offers different screening decision points to identify and narrow the number of product categories for consideration. Other screening methods exist and could be considered for this work plan or in the future by the Department. There is inevitable overlap between various approaches.

After screening decisions have been made using a given approach, DTSC would research available information on product formulations to identify product categories associated with any of the priorities identified using that approach.

Each approach relies upon both scientific analysis and the Department’s policy priorities. We ask the GRSP to advise us whether or not the proposed approaches provide the breadth of perspectives they recommended in April. Additionally we ask GRSP members to offer their assessment about the relative merits and potential challenges associated with these approaches.

1) Hazard Trait and Endpoint Screening Approach

The Department may decide to prioritize possible hazard endpoints (or associated endpoints)³ associated with product-chemical categories based on pressing public health or ecological health concerns. The Department may identify a number of endpoints and decide as a matter of policy that certain endpoints will be given special consideration during product category screening.

In the case of endpoint screening, the Department would make decisions about which of the wide range of endpoints it chooses to focus on. Screening decisions in this category entail prioritization of select endpoints for further product-chemical research. Screening decisions may be based on the strength of evidence linking consumer products to certain endpoints.

The Department is strongly considering identification of at least one ecological endpoint product category.

2) Route of Exposure Approach

By their nature, certain products directly expose consumers to candidate chemicals in normal use. For instance, products that rely on application to the body or that generate vapors that are readily inhaled become especially problematic if they contain toxic chemicals. The Department may select categories that include products whose normal mode of use poses high potential for exposure to any candidate chemicals they may contain.

3) Chemical Prioritization Approach

The Department may identify product categories that contain candidate chemicals it has prioritized as a matter of policy. A variety of factors could inform DTSC in prioritizing a particular chemical, including the chemical's exposure-response relationships, its volume in commerce, and its prevalence in multiple product sectors.

4) Evidence of Exposure Approach

The Department may review evidence of or concern about potential Candidate Chemical exposures. The Department may consider evidence such as (but not limited to)

- biomonitoring studies results or other studies of body burden,
- household dust studies results or other indoor media surveys,
- presence in environmental monitoring – in water, sediment, tissue, or blood, and
- indoor air monitoring results.

As in the other approaches, the Department would state that it had decided to focus on a particular line of evidence or route(s) of potential exposure as a matter of policy.

5) Sensitive Subpopulation Prioritization Approach

The Department may consider product categories relevant to certain sensitive subpopulations as defined in the SCP regulations.⁴ These include infants, children, pregnant women, and elderly and other individuals at greater

³ OEHHA has defined the breadth of endpoints and hazard traits for the Safer Consumer Products' regulation (Division 4.5, Title 22, California Code of Regulations Chapter 54).

⁴ 69501.1. (64) "Sensitive subpopulations" means subgroups that comprise a meaningful portion of the general population that are identifiable as being at greater risk of adverse health effects when exposed to one or more chemicals that exhibit a hazard trait and/or toxicological endpoint, including, but not limited to, infants, children, pregnant women, and elderly individuals. "Sensitive subpopulations" also include individuals at greater risk of adverse health effects when exposed to chemicals because they are either individuals with a history of serious illness or greater exposures to chemicals, or workers with greater exposures to chemicals due to the nature of their occupation.

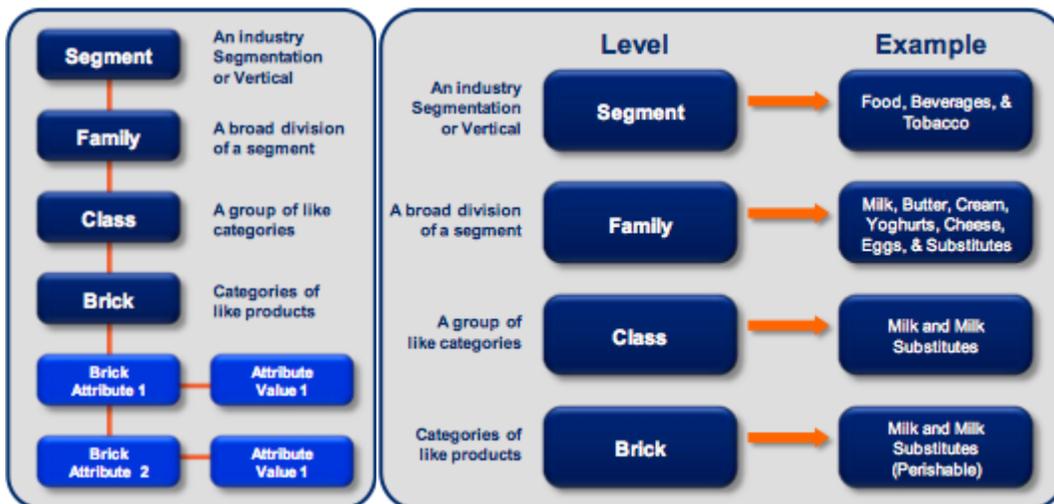
risk of adverse health effects when exposed to chemicals because they are either individuals with a history of serious illness or greater exposures to chemicals. In the SCP Program workers are also considered to be a sensitive subpopulation because they may be subject to greater exposures to chemicals due to the nature of their occupation.

6) Nomination Process Approach

The Department received many nominations of product-chemical combinations during the initial Priority Product selection process. A number of these nominated products were researched extensively but were not included in the Initial Priority Products List. These products warrant consideration for inclusion in the work plan. In addition to previously-nominated products, DTSC will likely receive new nominations of product-chemical combinations in the future. These nominations may be made formally or informally. The SCP regulations include a formal petition process (Article 4. Petition Process for Identification and Prioritization of Chemicals and Products), but interested stakeholders may suggest product categories or product-chemical combinations at any time.

Questions to the GRSP

1. What suggestions do you have to improve the initial approaches outlined above? Are there any anticipated challenges?
2. Are there other screening approaches the Panel thinks we should be considering? If so, what is the basis for the recommendation?
3. The Department invites panel members to make specific nominations or recommendations about product categories. If a product category is nominated, the Department is interested in the reason behind the nomination. Are there consumer products or product categories that are known to have strong linkages to particular endpoints? Are there lines of evidence that are particularly compelling?
4. Are there good methods, information sources and research tools that can help establish linkages between human health or environmental impacts and the consumer products? Are there documented indicators that have established that types of consumer products are impactful?
5. Does the Panel have insights and/or recommendations on how broad or specific the work plan product categories should be? A broader product category offers DTSC greater flexibility to select product-chemical combinations but a narrower product category may send a clearer signal to a more specific group of manufacturers. As an example, the following figure illustrates the taxonomy associated with Global Product Classification (GPC) codes for classification of products. This is one possible schema, but others exist outside of the GPC hierarchy.



<http://www.gs1.org/gdsn/gpc/what>

Final Product Category Selection

The SCP regulations provide the basis for final product category identification decisions. In addition to the two primary prioritization factors, decisions will be based on additional considerations such as impact on sensitive subpopulations, exposure factors, adverse waste and end-of-life effects, availability of information and review of other relevant regulatory authorities. Policy priorities and practical factors may also influence DTSC's selections.