Quantitative, Exposure-based Prioritization

July 1, 2011

ISSUE: To effectively achieve the Green Chemistry goal of significantly reducing adverse impacts on public health and the environment, hazardous chemicals and the products in which they are used must be prioritized, identifying the key contributors of exposure to target sub-populations and environmental receptors. This must be done in a practical and scientifically meaningful way.

SUMMARY: This paper describes a quantitative, exposure-based approach to prioritization of chemicals of concern and the products in which they are used to achieve the Green Chemistry goals of AB1879/SB509. This approach is science-based, outlining an integrated process to produce relative rankings for setting priorities for chemicals and the products in which they are used. It meets the prioritization mandates of AB1879—Department of Toxic Substances Control (DTSC) scientists would use volume, the potential for exposure and effects on sensitive subpopulations and the environment to identify human health and environmental priorities. The approach can effectively deal with hundreds of potential chemicals of concern and thousands of potential priority products to derive a ranked outcome. The ranking facilitates addressing the highest concerns first, within the limits of available Department resources. Transparency of the underlying assumptions and the results of the prioritization can be accomplished by making them available for public input through a formal notice and comment process. This approach is within the scientific capabilities of the Department and can be applied in a timely manner. It has been tested and found to be effective, efficient, practical and meaningful in meeting the objectives of Canada's prioritization mandate under the Canadian Environmental Protection Act (CEPA).

BACKGROUND: The prioritization of chemicals of concern and the products in which they are used is one of several core mandates of the 2008 Green Chemistry legislation (AB1879/SB509). The Department is directed "*...to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern*". The statute indicates that the process must address: "*(1) The volume of the chemical in commerce in this state, (2) The potential for exposure to the chemical in a consumer product, and (3) potential effects on sensitive subpopulations, including infants and children*". The statute further directs that "*In adopting regulations pursuant to this section, the Department shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes, so as to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state's economy.*"

Since the enactment of the Green Chemistry legislation, the prioritization mandate has been the subject of numerous workshops, stakeholder comments and most recently Green Ribbon Science Panel (GRSP) discussions. All stakeholders and the Department have expressed an interest in ensuring that the process identifies and addresses the most important impacts to human health and the environment.

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DTSC recently summarized the factors that could be considered in prioritization for chemical hazard (*extent to which chemical exhibits one or more hazard traits, toxicity, potency, effects on sensitive subpopulations and environmental receptors, etc.*) and factors for chemical/product exposure (*volume of the chemical in commerce, types of products containing the chemical, mode of application of the products, concentration of the chemical in the products, frequency and duration of use of the products, potential exposure scenarios and pathways for sensitive subpopulations and environmental receptors, magnitude, extent and impact severity of likely exposures and the product's relative contribution to the concerns related to the chemical, etc.*). These are all important and scientifically robust considerations for making prioritization decisions.

In drafting proposed regulations, DTSC identified criteria that would be the bases for prioritization decisions:

- *"...the greatest potential for consumers and environmental receptors to be exposed to the chemical in quantities that can result in adverse public health or environmental impacts."*
- *"...the greatest potential for public and the environment to be exposed to the Chemical of Concern contained in the product in quantities that can result in adverse public health or environmental impacts."*
- *"...the availability of Department resources"*

All of the above present a significant challenge to the Department. There may be hundreds of potential chemicals of concern, which are used as ingredients in thousands of potential priority products. The prioritization criteria and factors for decisions noted above necessitate a quantitative approach to prioritization.

While qualitative factors such as indications of presence in biological or environmental media and presence in consumer or sub-population products can be useful for initial screening to identify a pool of candidate chemicals or a pool of candidate products using the chemicals, these are only qualitative or binary factors (i.e., Yes/No) and cannot be effectively and meaningfully used in a scientific prioritization process. A quantitative prioritization process is essential to credibly address the above prioritization factors, to establish the scientific basis for prioritization decisions within the scope of available Department resources, avoiding arbitrary decisions and building stakeholder confidence.

Quantitative, Exposure-based Prioritization Process
Prioritization based on "...potential adverse public health or environmental impact" is an important component of proposed regulations. Prioritization in this context means setting up an order for selection—addressing the "worst first"—identifying those chemicals and products using the chemicals that have the greatest potential for exposure and adverse impact on human health or the environment. The question becomes one of knowing which could be "the worst", and targeting areas where significant improvements would be most effective, before moving on to initiate the alternative assessment task.

In California's proposed regulation, the key focus for this prioritization is "...the potential for consumers or the environment to be exposed to the chemical in quantities that can result in adverse public health or environmental impacts." Prioritization is thus the relative ranking of

chemicals in conjunction with categories of products where the chemicals are used based on the potential for exposure and potential for significant adverse public health or environmental impact.

The overall frameworks for chemical and product prioritization are shown in Attachment 1. An initial pool of candidate chemicals is identified for prioritization based on chemical volume and other qualitative indicators of exposure (e.g. biomonitoring, environmental monitoring) and on chemical hazards including those that impact sensitive subpopulations (e.g. CMR, PBT). There are a number of federal and international authoritative sources that can help to identify chemicals with these properties and with information on the indicators of exposure. The candidates are narrowed based on their manufacture/import and use in consumer products in the U.S. Chemicals with health concerns (e.g. CMR) are ranked for adverse health impact based on direct exposures from products as well as indirect exposure to the population via the environment. Chemicals with environmental concerns (e.g. PBT) are ranked based on adverse impact to the environment. DTSC would use the Health and Environmental chemical rankings to select proposed chemicals of concern. Product rankings are developed based on the relative contribution to human and environmental exposure from the products that use the proposed chemicals of concern. DTSC would use the health and environmental product rankings to select proposed priority products that use a chemical of concern.

Health Ranking. The task begins with a set of candidate chemicals that have human health concerns (e.g. CMR) and are used as ingredients in consumer products. The chemicals are ranked as to their potential to cause adverse impacts to different subpopulations that may use those products. The first step in ranking is to identify the functional uses of each candidate chemical using publicly available information. Product uses for each chemical are then grouped by their exposure features. The product(s) within each group that provide the greatest exposure (by age, gender, etc) are selected as "Sentinel products", which serve as the surrogate(s) for the group. Separately, these chemicals with human health concerns are also evaluated for their potential for indirect exposure through the environment via air, water and/or food. The exposures from Sentinel products using the chemical (across multiple product groups) are considered together with the indirect exposure via the environment to quantitatively rank each chemical's relative exposure and adverse impacts. The prioritization process yields chemicals ranked high to low in terms of public health impact and as a function of age, gender or other subpopulation from which DTSC would select proposed chemicals of concern to fit within available Department resources. The process also yields, in the second step, a ranking of products that use the proposed chemicals of concern from high to low as a function of age, gender or other subpopulation. DTSC would select priority products for Health from the sentinel products that make the greatest contribution to reducing a chemical's exposure and potential for adverse impact.

Environment Ranking. As a result of product use or end-of-life disposal practices for consumer products, there is a potential for release into, migration among and distribution of the chemicals of concern across environmental media such that exposure to environmental receptors may occur. Therefore, the first step in developing a ranking and prioritization based on adverse impact on the environment involves estimating environmental exposure levels in California, including estimating exposure to representative higher trophic level organisms of interest to the Department, using existing models and the volume of chemical released into the California environment. To develop the ranking based on adverse impact on the environment, these

estimated environmental exposure levels are compared to appropriate environmental toxicity endpoints. The ratio of the toxicity endpoint to the exposure level can be used to rank the potential for adverse impact—the higher the value of this ratio indicating the higher the priority for that chemical. The second step in the environmental prioritization is to develop a ranking for the products that use the proposed chemicals of concern. This process uses the information from the previous chemical prioritization as well as information on the relative product use volumes released to the environment for the various types of consumer products within which the proposed chemical of concern is used. DTSC would select priority products for the Environment that make the greatest contribution to reducing the volume and exposure of the chemical released to the environment and its potential for adverse impact.

Experience with these Approaches

Health Ranking. The Canadian Environmental Protection Act (CEPA) mandated that Health Canada screen and prioritize the Canadian chemical inventory based on "the greatest potential for exposure". In 2006, a prioritization tool based on exposure potential was developed (ComEt). A proof of concept trial was conducted for over 200 chemicals for which uses were identified, sentinel products selected, exposure information developed and health prioritization completed. Among the lessons learned was that extensive information was publicly available on most chemicals to support this process. Existing government and other databases provide abundant information and are becoming increasingly accessible. Tools exist for the estimation of indirect or secondary exposure to the California population through the environment. There are a number of well-recognized and accepted environmental models for these tasks e.g. CalTOX, RAIDAR, EUSES, FHX, that can be parameterized for California needs. Exposure-based prioritization can be accomplished in a time and cost-efficient way, yielding a science-based relative ranking of chemicals and products. The tools exist and the results can be made transparent and can be improved through public review and comment.

Environment Ranking. Tools exist for estimation of environmental exposure levels. There are a number of well-recognized and accepted environmental models for these tasks e.g. CalTOX, RAIDAR, EUSES, FHX. They are fully documented, publicly available and can be parameterized for California needs. The RAIDAR model was used to inform Canada's environmental prioritization of chemicals and has shown to be an efficient and effective tool for chemical prioritization.

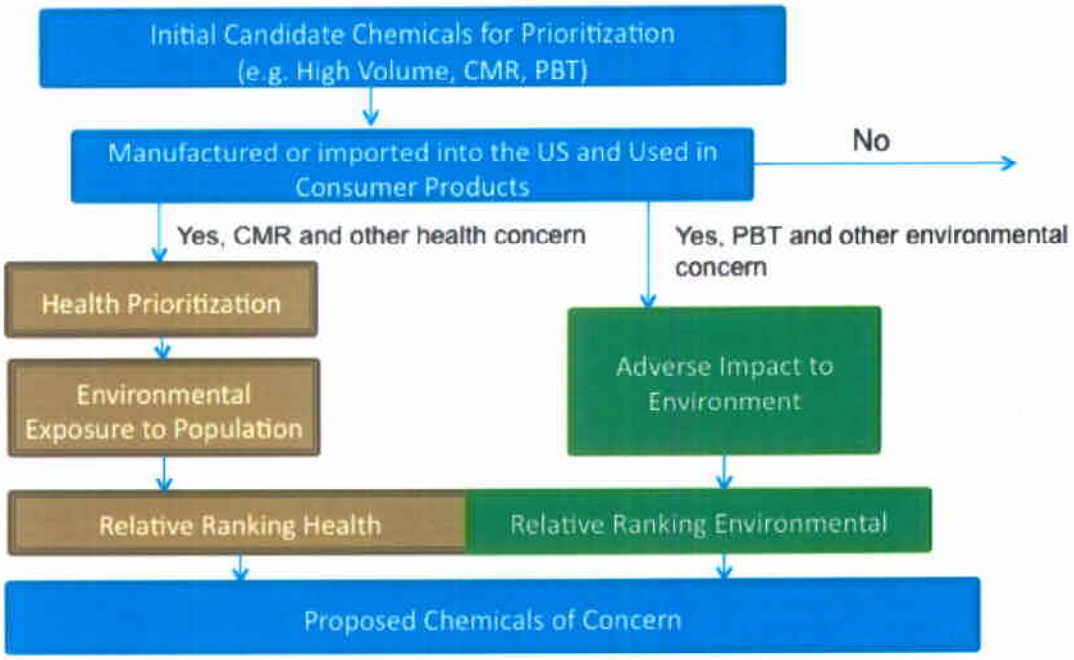
Conclusion/Recommendation

Relative ranking can accomplish the objectives of chemical and product prioritization for human health and the environment. The identification and use of Sentinel products in the health prioritization provides a practical and efficient approach to focus the work on the most important sources of potential exposure and adverse impact. The integrated process described is objective, science-based, meaningful, and transparent. It produces rankings based on quantitative comparisons of hazard and exposure, addressing both human health and the environment. It is responsive to the statute's requirements to consider volume, potential for exposure and sensitive subpopulations and complies with California's Administrative Procedures Act. It leverages existing, publicly available data and can deal with hundreds of potential chemicals of concern and thousands of products. The relative ranking outcome enables addressing the highest exposure with the most critical adverse impacts first. The number of chemical and product priorities selected would be dependent upon available Departmental resources. Results as well as underlying assumptions can be made transparent, and improved

through public notice and comment. This approach is within the scientific capabilities of the Department and can be applied in a timely manner. It has been tested and found to be practical in meeting the objectives of Canada's prioritization under the Canadian Environmental Protection Act. GMA recommends that the approach be adopted to achieve the Green Chemistry goal of significantly reducing adverse impacts on public health and the environment.

Attachment 1

Chemical Ranking Framework



Product Ranking Framework