

## ***Practical Decision-Making Tools for Identifying Safer Alternatives***

October 1 and 2, 2007

Byron Sher Auditorium, Cal/EPA Building

### ***Abstract***

The Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency (Cal/EPA) and the Center for Occupational and Environmental Health (COEH) of the University of California Berkeley are collaborating on a workshop on decision-making tools for predicting and rapidly evaluating the toxicity and exposure potential of chemical pollutants as part of Cal/EPA's Green Chemistry Initiative<sup>1</sup>. The workshop will support OEHHA's efforts to meet its mandate under SB 25 to prioritize Toxic Air Contaminants that disproportionately impact children and to provide assistance to other Cal/EPA Boards and Departments in identifying safer alternatives. The workshop will also assist OEHHA in determining which toxic chemicals are of the highest priority to assess under a number of different programs.

The primary goals of this workshop are to:

- Discuss and describe the kinds of data that are needed for a robust framework for identifying problem chemicals and safer alternatives; and
- Identify and review existing and emerging tools used in predicting toxicity and environmental fate and exposure and prioritizing chemical hazards.

Discussing these issues with leading experts will help California grapple with the challenge of how to effectively flag problem chemicals and determine better alternatives. The results of the meeting will feed into the development of a framework for identifying safer alternatives to toxic chemicals that will incorporate the best features of existing and emerging decision-making tools.

### ***Introduction***

The COEH chemicals policy report<sup>2</sup> and many others have called attention to the lack of information on chemical toxicity and ecotoxicity for the great majority of chemicals in commercial circulation, a problem characterized in the report as the "Data Gap." The Data Gap is a consequence of the fact that under the federal Toxic Substances Control Act, chemical producers are generally not required to generate adequate data on the toxicity and ecotoxicity of the substances they introduce into commerce (other than pesticides, food additives, and pharmaceuticals). The chemicals market therefore operates primarily on the basis of the function, price, and performance of chemicals, with much less attention to their hazardous

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<sup>1</sup> See <http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/index.cfm>

<sup>2</sup> See [http://coeh.berkeley.edu/news/06\\_wilson\\_policy.htm](http://coeh.berkeley.edu/news/06_wilson_policy.htm)

properties. The Data Gap has made it very difficult for governments, businesses, and the public to identify, prioritize, and mitigate chemical hazards.

Cal/EPA, OEHHA, the U.S. Environmental Protection Agency (U.S. EPA), and other government agencies must make decisions and provide advice on the public health impacts of chemicals in our environment in the absence of robust toxicological and exposure information. Businesses attempting to “green” their operations are faced with the same problem. For example, OEHHA has been working to advise the California Air Resources Board on alternative dry-cleaning processes to replace perchloroethylene and on replacement chemicals for reactive volatile organic compounds. Toxicological data are limited for most of the proposed alternatives, making traditional risk assessments difficult and very uncertain. Similarly, many businesses have been making efforts to remove serious health hazards from products or their operations, but are often unable to obtain adequate toxicological data to move forward.

In spite of these barriers to adequate toxicity information, government agencies and businesses still need to make decisions about chemical hazards, so a number of screening tools of varying complexity and utility have been developed to do so. The OEHHA-COEH workshop will review the various approaches that have been used by agencies and businesses to identify potential problem chemicals, prioritize chemical hazards, and identify safer alternatives.

The field of toxicology is rapidly progressing beyond the animal toxicity tests typically performed to evaluate the health effects of a chemical. Standard toxicological tests are time-consuming and resource-intensive. The OEHHA-COEH workshop will review new tools and toxicity assays that are becoming available. These include, for example, computational and predictive toxicity tools, such as quantitative structure activity analysis, high throughput toxicity assays, and receptor binding assays. By using these innovative approaches, the process for chemical hazard identification and assessment could be more rapid, more efficient, and less resource-intensive. These approaches could facilitate the efficient identification of problem chemicals emitted into the environment in California as well as safer alternatives.

### ***Conference framework***

This conference will take place over two days.

### **Welcome and Introduction**

The goals of the workshop will be outlined here, along with the key issues to be addressed. The motivation for moving away from complete reliance on traditional, time-consuming toxicology testing toward the use of more efficient screening tools for identifying safer alternatives will be discussed. The regulatory and legal hurdles to moving forward with using screening tools to make public policy decisions will be highlighted.

**Session One: Existing Chemical Prioritization Approaches**

Session One will explore strengths and weaknesses of existing chemical prioritization approaches used by government and businesses to identify potential problem chemicals, and identify safer alternatives. We will hear from experts on how a number of approaches are currently applied. We will also explore how these tools can or cannot account for emerging data on evidence of very low-dose effects, chemical mixtures, genetic variability, effects at differing developmental stages, and exacerbation by other environmental factors.

*Topics and speakers for Session One:*

- OEHHA's screening process for identifying priority Toxic Air Contaminants for children's health in California (Melanie Marty, OEHHA)
- Prioritization under the Canadian Environmental Protection Act (George Enei, Environment Canada; Karen Lloyd, Health Canada)
- Prioritization under REACH (Richard Denison, Environmental Defense )
- Implementation issues under the recently adopted REACH regulation (Ninja Reineke, World Wildlife Fund)
- Green Screen for Safer Chemicals (Mark Rossi, Clean Production Action)
- Legal/regulatory barriers to using new screening tools (Michael Wilson, UC Berkeley)

Session One Panel: Screening for Safer Alternatives - Strengths, Weaknesses and Common Threads in Current Frameworks

Speakers from Session One

**Session Two: Predictive Tools for Toxicology and Exposure**

Session Two will explore the technical aspects of existing and emerging Quantitative Structure Activity Relationship (QSAR) methods and new toxicity assays that could be used by California to advance chemical hazard identification. We will hear from experts on how predictive QSAR tools are applied by the U.S. Food and Drug Administration (FDA), U.S. EPA, and others to evaluate chemicals with little toxicological data. The strengths and limitations of various screening tools will be highlighted. We will also hear from experts utilizing tools to predict potential for exposure of the general population to chemicals used in commerce. Finally, we will explore the development of high throughput screening assays and how they may be used in the future to predict toxicity of chemicals with little to no traditional toxicity testing data.

*Topics and speakers for Session Two:*

Predictive and computational toxicology tools

QSAR tools used by FDA (Edwin Matthews, FDA)

QSAR tools used by U.S. EPA (Tala Henry, U.S. EPA)

Tools for predicting exposure potential

Tom McKone, Lawrence Berkeley National Laboratory

Cathy Fehrenbacher, U.S. EPA

The future of toxicity testing - Lauren Zeise, OEHHA

Session Two Panel: Strengths and Limitations of Existing Predictive Tools and Views to the Future

Speakers from Session Two

**Session Three: Framework for Identifying Safer Alternatives – A Facilitated Discussion**

Session Three will be a facilitated discussion among speakers and other invited panelists. The discussion will focus on outlining a framework for identifying safer alternatives to toxic chemicals. Issues that would arise in the application of QSAR tools, tools for predicting exposure potential, and utility of emerging tools (*e.g.*, high-throughput toxicity assays) to current regulatory programs and policy initiatives within California will be highlighted. The panel may also address other contemporary issues in chemicals policy that should be woven into the framework, including emerging health endpoints of concern (*e.g.*, endocrine disruption), and children's health.

Session Three Panel:

All speakers from Sessions One and Two

Facilitator: Amy Kyle, UC Berkeley