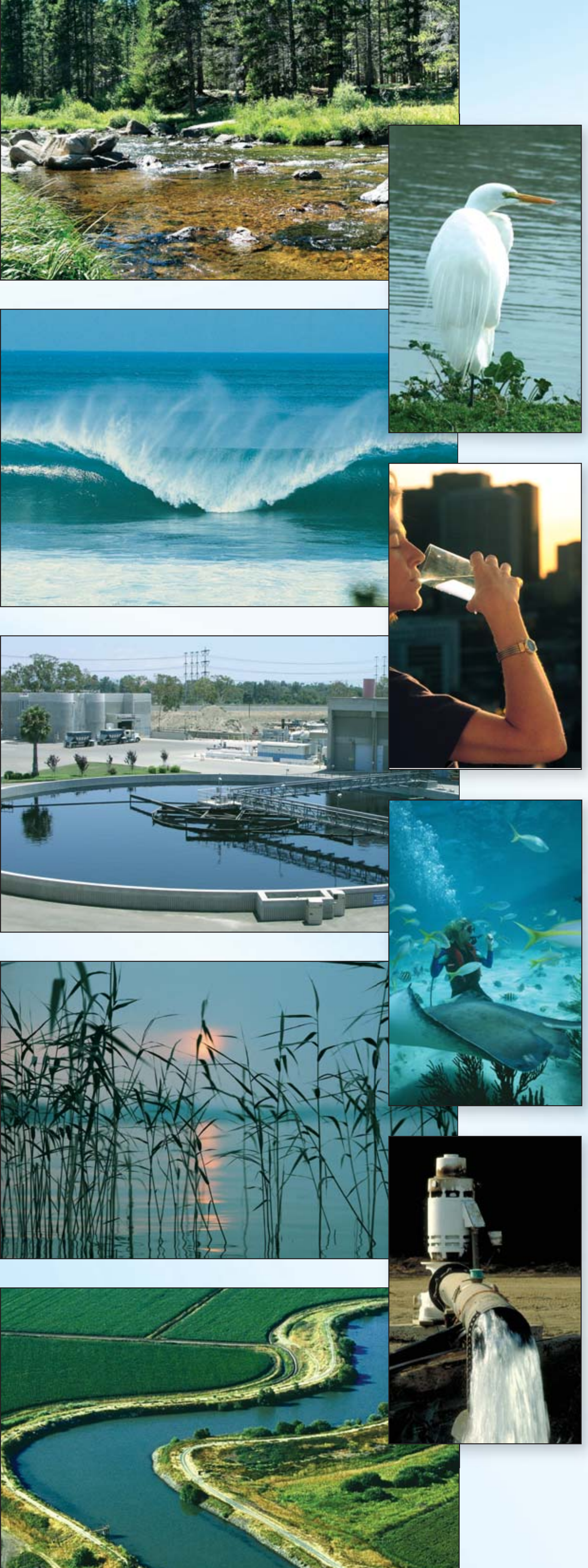

WORKSHOP REPORT

Managing Contaminants *of* Emerging Concern *in California*

Developing Processes for Prioritizing, Monitoring, and Determining Thresholds of Concern

April 28-29, 2009

COSTA MESA, CALIFORNIA

Workshop Report

Managing Contaminants of Emerging Concern in California: Developing Processes for Prioritizing, Monitoring, and Determining Thresholds of Concern

Sponsored By:

California Ocean Protection Council
California Ocean Science Trust
National Water Research Institute
San Francisco Estuary Institute
Southern California Coastal Water Research Project
University of California, Irvine – Urban Water Research Center

September 2009

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- California Ocean Protection Council (www.opc.ca.gov)
- California Ocean Science Trust (www.calost.org)
- National Water Research Institute (www.nwri-usa.org)
- San Francisco Estuary Institute (www.sfei.org)
- Southern California Coastal Water Research Project (www.sccwrp.org)
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Disclaimer

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The opinions, findings, conclusions, or recommendations expressed in this report reflect ideas and discussions brought forth at the Workshop. They do not necessarily reflect the opinions of the sponsoring agencies. This report was published for informational purposes only.

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Executive Summary

Contaminants of emerging concern (CECs) are a diverse group of relatively unmonitored and unregulated chemicals found in consumer and industrial products that have been shown to occur at trace levels in wastewater discharges, ambient receiving waters, and drinking water supplies. CECs include pharmaceuticals, personal care products, and other commercial and industrial compounds. A lack of basic information and the technology to efficiently measure CECs at trace levels (i.e., parts per trillion) hampers our ability to assess their potential risks, though scientists are beginning to generate such information. State and local health and regulatory agencies are aware of (and, in some cases, are funding this research), but have not yet synthesized the information into a comprehensive strategy for developing their monitoring and regulatory actions. A number of workshops have been held where scientists shared results among themselves and charted future directions for their scientific investigations on CECs in water, but there have been few mechanisms for the interaction between scientists, water quality managers, and other stakeholders.

In response, a workshop was convened to bring together 50 scientists, water quality managers, and stakeholders to enhance communication and formulate a path forward for integrating science into an effective CEC management strategy that is protective of water quality. Although the Workshop reviewed information on a national basis, the focus of the Workshop was devoted to approaches and recommendations on CECs in California.

The Workshop included plenary presentations that summarized the state-of-the-science and informed participants about regulatory practices for waterborne contaminants, and breakout sessions intended to review CEC approaches for California. Specific breakouts discussions were held on: 1) CECs that are of sufficient concern to be incorporated into routine monitoring programs, 2) measurement techniques for monitoring these CECs, and 3) thresholds of ecological and human health concern for interpreting CEC monitoring data.

Workshop participants began by agreeing that the *current chemical-specific risk assessment approach is neither feasible nor cost-effective for prioritizing and managing the vast majority of CECs*. The participants noted that chemical-specific risk assessment approaches will continue to play a role in the regulation of contaminants for those chemicals with known adverse effects. There are 129 priority chemicals currently regulated by the USEPA under the Safe Drinking Water Act and Clean Water Act, but tens of thousands of CECs exist that may potentially require assessment to ensure their impacts to human and ecological health are minimal. The traditional risk-based approach can be retained for those CECs for which detailed information on occurrence, concentrations, exposure, and toxicity (e.g., dose-response relationships) is available; however, this current paradigm is not feasible given the extreme data gaps for most CECs and the limited resources available to fill these gaps. A new paradigm which prioritizes chemicals (or chemical classes) with similar modes/mechanisms of action for further evaluation is needed.

Monitoring of CECs is a key part of that new paradigm, but Workshop participants stressed that *we are currently in the investigative phase, and developing regulatory limits would be premature at this time*. Identifying a clear set of goals for investigative monitoring (e.g., to address unanswered questions on CEC occurrence and concentrations, or to assess the removal efficiency of existing or new treatment processes) was deemed essential for filling the most critical data gaps and obtaining maximum benefit from the limited resources available to support such studies. Because trace levels of CECs may impact multiple beneficial uses of water (e.g., human consumption and ecological health) in a variety of settings, a set of priority questions specific to the monitoring application were developed to guide future data collection. These applications included protection of human health and/or ecosystem health in drinking water supplies, recycled water for non-potable and potable reuse, wastewater discharge, and stormwater runoff. By delineating these applications, the participants were able to identify commonalities in data collection needs across different sectors of the water resources community and highlight areas of potential collaboration.

Owing to the scarcity of data and lack of robust methodologies for measuring most CECs, *a flexible, multi-element prioritization framework was recommended to identify those compounds of highest concern.* This framework would integrate risk-, occurrence-, and modeling-based prioritization elements to select the highest priority CECs for each specific monitoring application and geographical location. Priority CEC lists could be further optimized by incorporating indicator compounds and/or surrogate parameters, which serve to enhance the effectiveness of monitoring approaches while reducing the cost and complexity of monitoring. While analytical methods exist for some CECs, the development of robust techniques at trace levels for additional chemicals is needed to provide a solid foundation for monitoring programs. Since it is impractical to develop analytical methods for thousands of individual CECs, the use of appropriate indicators and surrogates to help meet monitoring goals was encouraged. In addition, there is a likely need to complement chemical testing by developing and testing high throughput bioanalytical methods that can integrate the activity of multiple toxicants into a single mode-of-action based response.

The participants overwhelmingly agreed that creation of a single master list of CECs that agencies could apply effectively across all applications was unlikely. Instead, participants concluded that the logical next step in this process will be to formulate *preliminary lists* of priority CECs, indicator compounds, and surrogate parameters that will address the investigative monitoring goals for the various applications, including drinking water, recycled water (non-potable and potable reuse), wastewater discharges, and ambient receiving waters. These preliminary lists could then be incorporated into existing and/or planned collaborative studies that are organized at the watershed or regional scale. Results from these pilot studies will be used to fill key data gaps and initiate the iterative process formulated during the Workshop for prioritizing those CECs in need of regulatory review.

Interpretation of monitoring data and subsequent decision making should be based on tiered, multiple thresholds. Thresholds associated with no, little, moderate, and high probabilities of impact should be used to trigger risk-appropriate actions aimed at protecting beneficial uses of the resource. In concert with the proposed risk-based prioritization framework, the participants stressed that development of effects-based thresholds should consider mode-of-action, as well as the distribution of dosages that elicit the response of interest.

Participants also emphasized that we are early in the CEC evaluation process and *an adaptive management strategy is imperative to respond to rapidly changing knowledge.* There was also a general consensus that trust among water quality managers, scientists, and the public is a key component in moving this process forward. Developing a communication plan that fosters transparency in setting goals, minimizes inappropriate use of investigative monitoring data, facilitates timely response to changing information, and provides ample opportunities for candid and objective discourse across stakeholder communities was endorsed by the participants.

1. INTRODUCTION

Summary:

- The number of CECs is large, and their global inventory is increasing; detections at trace levels are expected to increase as new analytical methodologies are developed.
- Selected CECs at trace levels may be cause for concern, but little information is available to assess risks for the majority of CECs.
- The Workshop brought together leading scientists and managers to discuss a strategy to begin monitoring and addressing CECs in California, despite current knowledge gaps.

1.1 There are thousands of CECs

Contaminants of emerging concern (CECs) are a diverse group of relatively unmonitored and/or unregulated chemicals whose potential to impact beneficial uses of water resources in California is largely unknown. Pharmaceuticals and personal care products (PPCPs), current use pesticides, and industrial compounds (e.g., halogenated organic compounds, siloxanes, etc.) constitute the majority of chemical types that are commonly considered CECs, primarily due to their high volume use and potential for biological activity in non-target species (Kidd et al., 2007) and the increasing number of studies that report their occurrence in drinking water sources (Benotti et al., 2009) and natural aquatic environments (Bay, 2008).

Approximately 100,000 chemicals have been registered for use in the United States over the past 30 years, which include the substances listed in the United States Environmental Protection Agency (USEPA) Toxic Substances Control Act inventory [industrial chemicals (~82,000), food additives and cosmetics ingredients (~9,000), pharmaceuticals (~1,000), and pesticides (~1,000 active ingredients); Muir and Howard, 2006; **Fig. 1]**. Between 2002 and 2005, there was an 80% increase in the volume of chemicals produced or imported in the United States, with the total volume estimated at 27 trillion pounds (Wilson and Schwarzman, 2009). Further increases are anticipated, as global chemical production is expected to increase at a rate of 3% per year (Wilson and Schwarzman, 2009).

In contrast to the staggering number of chemicals in use, our capability to measure trace levels of CECs in the environment is currently limited to several hundred individual analytes. For example, recently developed and/or published methods based on state-of-the-art instrument technology are limited to approximately 70 to 100 PPCP analytes (USEPA, 2007; Benotti et al., 2009). This is not to suggest that analytical methods are needed for most/all commercial chemicals, as many are intentionally or unintentionally transformed during production, product manufacture, use, and disposal. Rather, the limited pool of analytical methods restricts the ability of researchers to accurately describe CEC occurrence.

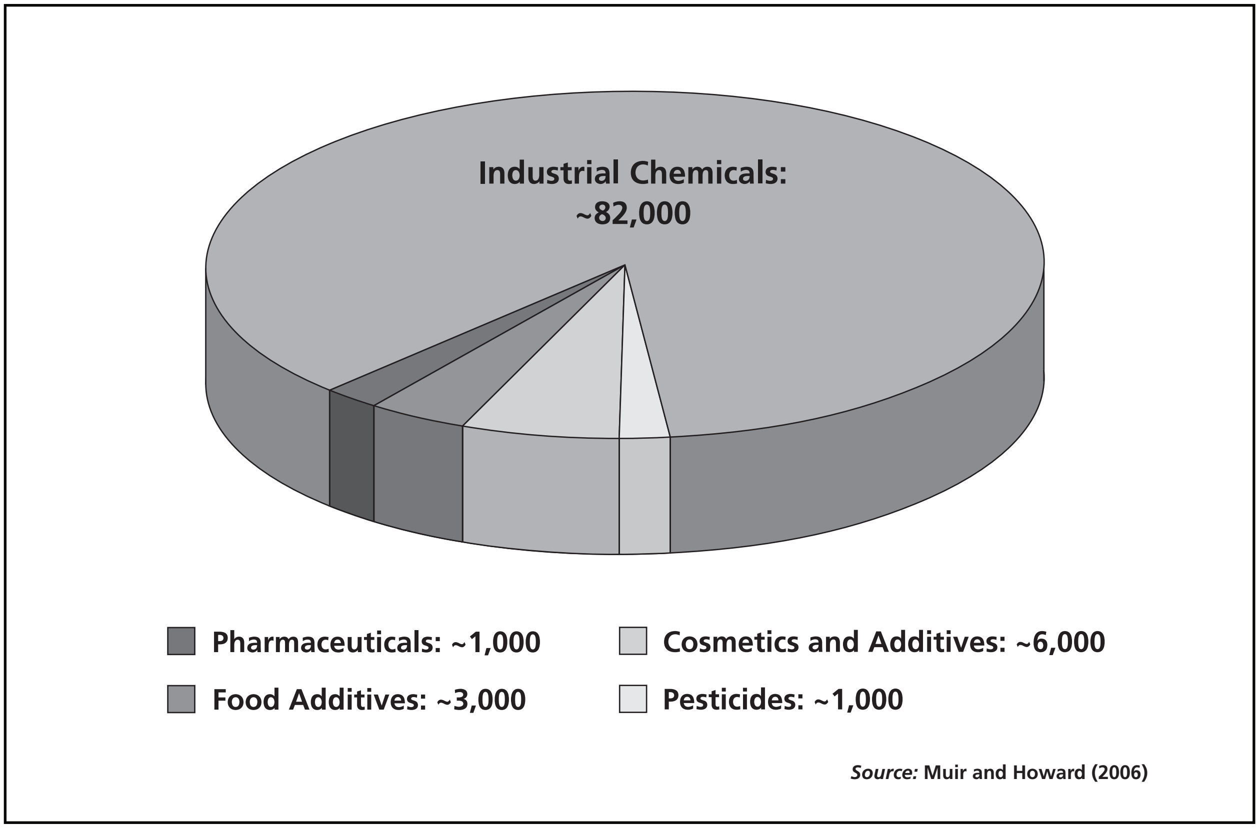

Figure 1. *Approximately 100,000 individual chemicals have been registered for commercial use in the United States over the past 30 years. Chemical classes that receive the majority of public attention (e.g., pharmaceuticals, cosmetics and food additives, and pesticides) constitute only a small percentage of this inventory. Analytical methodologies are currently limited to several hundred of these non-regulated chemicals.*

1.2 Information gaps limit science-based decision making

A lack of basic information and the technology to efficiently measure most CECs hampers the ability of researchers to assess the potential risks associated with these chemicals. For many chemicals, complete information about their applications and product-specific uses are unavailable, making it difficult to ascertain the probability of exposure for people and wildlife. Researchers tend to focus on chemicals deemed to be a high priority risk for society before developing analytical methods to monitor them in people and the environment, and in turn to conduct chemical fate and toxicity experiments. Chemicals are often released in large quantities and become diffusely distributed before adverse effects on people and the environment are observed. This makes it difficult to pre-emptively target emerging chemicals for monitoring and control.

Much of the data available for CECs have been generated by companies as a result of regulatory requirements (e.g., the United States Food and Drug Administration (USFDA) or the USEPA). These data are useful, but tend to include little-to-no information on chronic toxicity for low-level exposures, toxicity in non-target species (particularly for pharmaceuticals), or sensitive toxicological endpoints, such as endocrine disruption potential. In addition, much of the information, including the chemical identities in commercial formulations, is characterized as confidential business information and unavailable for public review. As a result, relevant risk assessment and toxicity thresholds often cannot be developed.

Knowledge of a chemical's fate and potential for toxicity, including an understanding of the potential implications to humans and wildlife from both short- and long-term exposure, is necessary for government agencies to establish chemical concentrations that are protective of human and ecological health. For legacy chemical contaminants, such as polycyclic aromatic hydrocarbons (PAH), polychlorinated biphenyls (PCBs), and mercury, sufficient data exist to establish environmental thresholds and regulations with an acceptable degree of uncertainty. Well-defined endpoints, such as cancer risk, form the basis for setting thresholds and regulations of these priority pollutants. In contrast, basic information regarding the occurrence, persistence, and degradation products in the environment is unavailable for the majority of CECs in use. Moreover, knowledge of toxic modes and/or mechanisms of action for most CECs is minimal. This knowledge is crucial for establishing exposure and risk thresholds that ultimately serve to protect the most important beneficial uses of water resources and aquatic ecosystems.

For the specific instances where sufficient data exist, extension of the current risk-based approach may show that some CECs may cause impacts at very low environmental concentrations. One well-publicized example is the apparent feminization of male fish and subsequent collapse of a population of a single fish species in a closed experimental lake system dosed with parts per trillion levels of the synthetic hormone 17α-ethinylestradiol (EE2; Kidd et al., 2007). This work indicates the need for vigilance when assessing the potential impacts of low-level CECs and highlights the inherent difficulty in constructing the risk assessment paradigm for CECs. In this case, the chemical impact was not a toxic endpoint, but one of reproductive impairment that led to second generation population-level impacts.

1.3 Integrating science into management: The California CEC Workshop

Many state and local regulatory agencies that deal with environmental quality issues are generally aware of (and, in some cases, funding) CEC research, but most have not yet synthesized the vast amount of information into a comprehensive strategy for developing their monitoring programs and regulatory actions. In response to the information needs expressed by multiple governing bodies in the State of California, a workshop was organized and sponsored by the following organizations:

- California Ocean Protection Council
- California Ocean Science Trust
- National Water Research Institute (NWRI)
- San Francisco Estuary Institute (SFEI)
- Southern California Coastal Water Research Project (SCCWRP)
- University of California Irvine, Urban Water Research Center (UWRC)

The Workshop was held on April 28-29, 2009, in Costa Mesa, California. In contrast to conferences and/or symposia that focus primarily on science issues, the purpose of this workshop was to provide a forum for dialog among the research, regulator, and stakeholder communities to prioritize and integrate the science needed to formulate an effective statewide CEC management strategy (see *Appendix A*). The primary goals of the Workshop were to delineate processes that the State should employ to:

- Identify which CECs are of sufficient concern to be incorporated into routine monitoring programs.
- Standardize the monitoring programs and analytical techniques that will be used for monitoring priority CECs.
- Determine thresholds of ecological and human health concern for interpreting CEC monitoring data.

More than 50 scientists, regulators and water quality managers attended the Workshop (see *Appendix B*), which included plenary presentations summarizing state-of-the-science research, current State regulatory practices for waterborne contaminants, and water quality challenges that unmonitored CECs present to management. Attendees participated in concurrent breakout group sessions (two each for ecological and human health specialists) to develop processes to guide the future actions of State, regional, and local water quality managers.

1.4 Synthesizing the Workshop outcomes

This report summarizes the findings of the Workshop, challenges to implementation that were identified, and the recommended next steps towards developing recommendations on a CEC management strategy for California. The intent was to capture the key points, approaches, and studies discussed and brought forth by the Workshop participants and to synthesize the outcomes of the breakout sessions into a coherent process by which CECs can be effectively managed in California. The target audience for this report is the management and scientific communities.

Whereas the Workshop breakout sessions were held sequentially, the participants noted that the three major topics could not easily be partitioned and discussed independently of each other (see Agenda, *Appendix A*). Rather than address these topics in strict order, the remaining sections of this report first address the current state of CEC science and decision-making capabilities, as well as the need for a new management paradigm (Section 2). The report next delineates a process for developing a CEC monitoring strategy, first by identifying and setting clear goals that are tailored for specific monitoring applications (Section 3), followed by a description of a CEC prioritization framework that incorporates existing knowledge, the flexibility to deal with constituents for which much or very little is known, and the importance of identifying potential surrogates to streamline monitoring efforts (Sections 4.1-4.2). Section 4 concludes with a description of the type of tools needed for effective CEC monitoring and a tiered framework for data interpretation. Key challenges that must be overcome to effectively manage CECs are spelled out in Section 5. The report concludes with a list of activities recommended by the Workshop participants that can be implemented within the State in the near term to move this process forward (Section 6).

2. A NEW CHEMICAL MANAGEMENT PARADIGM

Summary of Workshop findings:

- Current chemical management frameworks were not designed to address CECs.
- Prioritizing most CECs will require new approaches.
- Because it is early in the process, current activities in California should focus on investigative, rather than regulatory, monitoring.

2.1 Existing risk paradigms do not work for CECs

There are 129 priority chemicals currently regulated under the Clean Water Act and additional chemicals regulated under the Safe Drinking Water Act, but there are tens of thousands of CECs that may potentially require assessment to ensure their impacts to human and ecological health are minimal. The traditional risk-based approach to prioritizing chemicals for inclusion on priority monitoring lists requires detailed information on exposure and toxicity (e.g., dose-response relationships; **Fig. 2**). Given the extreme data gaps for CECs, the limited resources available to fill these gaps, and the increased use and number of chemicals each year, Workshop participants felt that it is infeasible and not cost-effective to rely solely on the current, chemical-specific approach to prioritize CECs. Ideally, the new paradigm will include a process to efficiently prioritize chemicals, or chemical classes with similar modes/mechanisms of action, for further evaluation, as well as a process for assessing a wide range of potential impacts in wildlife and people as a result of chronic, low-level chemical exposure.

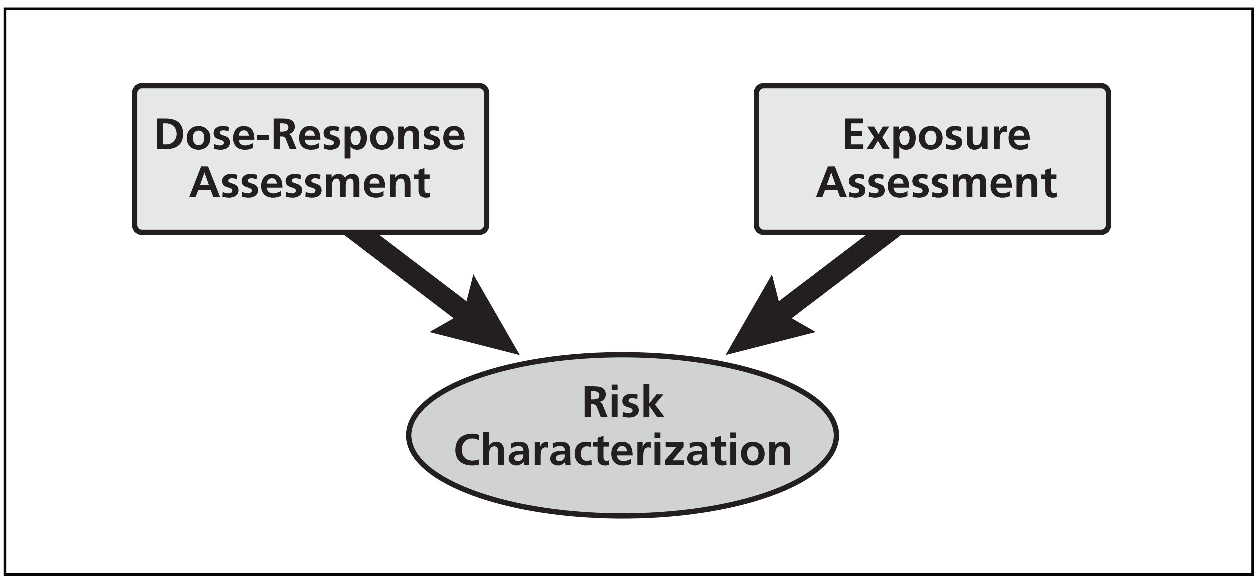

***Figure 2**. The traditional risk-based paradigm for identifying specific chemicals of concern cannot process the enormous number of CECs in use, nor is it cost-effective to generate the volume of dose-response data (e.g., for multiple effects endpoints) needed to adequately characterize risks on a case-by-case basis using this model.*

2.2 We are early in the process

Because a new paradigm is needed for prioritizing CECs and much of the most pertinent information has not yet been generated, the process of formulating a formal management strategy for CECs is clearly in the early stages. In lieu of regulations or compliance monitoring, the Workshop participants stressed that *investigative* chemical monitoring should be used as a first step towards the development of a management strategy in California. The first step in this investigative phase is to establish a clear set of goals for monitoring, and to define appropriate as well as unacceptable or inappropriate uses of the data. As the science will continue to evolve during this phase of the process, the opportunity to review and interpret monitoring data should be provided (Section 5.3 *Adapt to the moving target*).

Recently, information useful for the development of a new strategy has become available with the reporting of chemical prioritization frameworks and CEC priority lists by various research groups at the state, national, and international levels (see Section 4.1 *Don't reinvent the wheel*). California is also in the process of identifying priority chemicals, which include some CECs, for its human biomonitoring program. A substantial amount of science is beginning to fill data gaps on CEC fate and toxicity in the environment, with a large amount of research specifically aimed at developing more efficient methods, including bioanalytical techniques that incorporate the latest in biomolecular knowledge and technology for predicting impacts (see Section 4.3.1 *Select the right combination of analytical tools*).

3. ESTABLISHING MONITORING GOALS

Summary of Workshop findings:

- Identifying specific applications and motivations for monitoring clarifies commonalities and differences in goals among sectors of the water resources community.
- Goals for monitoring programs should address beneficial uses.

3.1 Define the applications for monitoring

One of the keys to effective management is a monitoring program that provides valuable information on the extent and magnitude of the occurrence of CECs in water supplies, receiving waters, and permitted discharges. A basic understanding of the system to be monitored and the requirements driving this need – a "monitoring application" – are essential for establishing meaningful monitoring goals. From a regulatory and monitoring perspective, waters that provide benefit to humans and ecosystems can be classified into the following categories – drinking water, recycled water (including non-potable and potable reuse), stormwater, permitted discharge (e.g., treated wastewater effluent), and ambient waters. In practice, the types of water that are subject to water quality regulation include:

- Drinking water.
- Recycled water for indirect potable reuse (e.g., groundwater recharge and surface water augmentation).
- Recycled water for non-potable reuse (e.g., landscape and agricultural irrigation, commercial and industrial process water, toilet flushing).
- Treated wastewater (effluent).
- Stormwater.
- Surface water.
- Groundwater.
- Ocean water.

Regulatory drivers for chemical compounds also differ across these systems, falling into four main categories: 1) protection of human health, 2) protection of ecological health, 3) assessment of the effectiveness of treatment processes designed to remove regulated constituents, and 4) identifying unknowns or dramatic changes from background levels.

The Workshop participants proposed combining the common systems with the appropriate regulatory driver(s) in a simple monitoring application matrix (**Table 1**) that provides several benefits. It allows for similarities and differences among the applications to be compared and contrasted by the respective stakeholders. If, for example, a priority CEC is found to occur in both drinking and ambient waters at levels of concern, stakeholders from those communities could partner to identify the best available monitoring tools/technology, share the latest toxicological information to better assess the degree and/or likelihood of impact, and collaborate on control or mitigation strategies. This matrix also serves as an outline in developing application-specific monitoring designs, including preliminary lists of high priority CECs and methods, as well as measurement timing, frequency, and spatial coverage. One of the most important benefits of this approach is that it identifies those applications that can be addressed at the regional scale. Lastly, this parsing approach facilitates effective risk communication by identifying the appropriate target audience (see Section 5.1 *Effective communication is key*).

***Table 1**. Defining the Water Systems and Driving Requirement(s) for Monitoring Clarifies Goals, Identifies Commonality, and Facilitates Risk Communication*

Monitoring Application	Ecological	Human Health	Treatment Performance
Potable *(i.e., drinking water supply)*	No	Yes	Yes
Indirect Potable Reuse *(e.g., recycled water for groundwater recharge and surface water augmentation)*	Varies	Yes	Yes
Non-Potable Reuse (e.g., *recycled water for landscape irrigation, agricultural irrigation, and urban, industrial, and commercial uses*)	Varies	Varies	Yes
Permitted Discharge *(e.g., treated wastewater effluent or stormwater runoff)*	Yes	Yes	Yes
Ambient/Receiving Waterbody *(e.g., stream, reservoir, estuary, ocean)*	Yes	Yes	No

3.2 Establish monitoring goals to protect beneficial uses

In response to the federal Clean Water Act and similar to other states, California has narrative descriptions for the beneficial uses of its waters that encompass the following questions:

- Are our water supplies safe to drink?
- Are fish safe to eat?
- Are recreational waters safe to swim in?
- Is the ecosystem healthy?
- Are treatment processes effective and working properly?

Whereas the above questions apply to contaminants in general, the most pertinent questions for CEC monitoring programs were expressed by Workshop participants as:

- Are CECs present in drinking water sources, in recycled water, and in the environment?
- Are CEC levels in drinking, recycled, and receiving waters cause for concern?
- Are regulations protective of public health and the environment?
- Are new persistent CECs accumulating in the food web?
- Are CECs in treated wastewater effluent causing significant ecological effects (e.g., endocrine disruption in fish)?
- Are CECs in stormwater runoff toxic to wildlife?
- Are new CECs occurring?

Properly designed and implemented monitoring programs for CECs will provide the data to answer these questions. In addition, these programs and studies will provide information to address a number of supporting goals, including:

- Promoting proactive science.
- Providing baseline information for spatial and temporal trends (e.g., are levels increasing or decreasing?).
- Allowing comparison and evaluation of best management practices.
- Enabling risk communication.
- Developing appropriate regulatory and policy decision support tools.

4. DEVELOPING THE MONITORING FRAMEWORK

Summary of Workshop findings:

- Existing CEC priority chemical lists, monitoring frameworks, and their objectives should be considered in developing CEC monitoring approaches in California.
- Because of the scarcity of data and/or lack of methodologies, a flexible, multi-element framework for prioritizing CECs is recommended, including risk-, occurrence-, and modeling-based prioritization elements.
- A monitoring framework that is flexible and regional in scope is desirable.
- Since a single "master" list of CECs will not be applicable to all situations, priority lists should be developed specific to each monitoring application.
- Indicator compounds and/or surrogate parameters that mimic the behavior and fate of priority CECs should be utilized to enhance the effectiveness and reduce the cost and complexity of monitoring.
- Candidate analytical methods for monitoring of priority CECs should be "risk appropriate."
- Bioanalytical "screening" tools that integrate the activity of multiple toxicants into a single mode-of-action based response are needed to supplement chemical methods.
- Interpretation of monitoring data should retain flexibility and is best guided by a tiered, multiple threshold approach.

4.1 Don't re-invent the wheel

Although CEC management itself is in its infancy, the scientific and regulatory communities have performed critical research and developed initial candidate prioritization frameworks to understand and address the potential for impacts (e.g., Muir and Howard, 2006, Benotti et al., 2009). A substantial amount of science is beginning to fill data gaps on CEC fate and toxicity in the environment, with a large amount of research specifically aimed at developing new, more efficient methods for predicting impacts, including bioanalytical techniques that incorporate the latest in biomolecular knowledge and technology. A number of frameworks, initiatives and policies at the state, federal, and international level have been developed and/or adopted to date, including:

- Oregon's SB737 list of persistent, toxic, and bioaccumulative or "PBT" chemicals.
- Washington's Department of Ecology "PBT" Initiative.
- Maine's Chemicals of High Concern List.
- USEPA's Drinking Water Candidate Contaminant List 3 (CCL3).
- USEPA's ToxCast program.
- USEPA's Great Lakes prioritization framework for persistent & bioaccumulative chemicals.
- Canada's Domestic Substances List Categorization.
- The European Union's Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (REACH).

California has been among the most proactive states in terms of regulatory guidance and activities that aim to quantify, characterize, and limit the potential for impact of CECs. Several pilot-scale investigative monitoring studies on CECs in water supplies, treated drinking water, and ambient receiving waters have been completed, or are currently underway throughout the state, including:

- *Proposition 65* – Listing of chemicals known to cause cancer, birth defects, or other reproductive harm. This list contains more than 750 naturally occurring and synthetic chemicals, and includes additives or ingredients in pesticides, common household products, food, drugs, dyes, or solvents.
- *Green Chemistry Initiative* – Aimed at expanding pollution prevention; developing green chemistry workforce education, training, research, and technology development; creating an online product ingredient network; creating an online toxics clearinghouse (SB 509); accelerating the quest for safer products (AB 1879); and moving toward a cradle-to-cradle economy.
- *Environmental Contaminant Biomonitoring Program* – With long-term goals designed to determine baseline levels of environmental contaminants in a representative sample of Californians, establish time trends in chemical levels, and assess the effectiveness of current regulatory programs, the program is currently focusing on community exposures to environmental chemicals.
- *Recycled Water Policy* – To establish uniform requirements for the use of recycled water. This includes a research program which convenes a Blue Ribbon Panel to address salient issues and make recommendations to the State Water Resources Control Board, so as to guide future regulatory actions with respect to CECs.
- *Emerging Contaminants Workgroup, Regional Monitoring Program for Water Quality in the San Francisco Estuary (SFEI)* – The goal of this workgroup is to determine what CECs have the greatest potential to adversely impact beneficial uses in San Francisco Bay. Research conducted to date includes annual monitoring of sediment, water, and biota for polybrominated diphenyl ethers (PBDEs), an evaluation of the alternative flame retardants (PBDE replacements), monitoring for pharmaceuticals in effluents and bay water, and evaluation of perfluorinated compounds in a number of biological matrices.
- *West Basin Seawater Barrier Water Conservation Project* – An independent review of a seawater intrusion barrier project for a drinking water aquifer. It developed a set of criteria to select 12 chemicals for monitoring in injection water that could indicate a breach of one or more of the treatment barriers used to remove trace contaminants.
- *Emerging Contaminants Workgroup, Santa Ana Watershed Protection Agency (SAWPA)* – This workgroup is charged with defining goals of a CEC monitoring program for ground, surface, and recycled/reclaimed water. It will also survey the ability of commercial labs to fulfill monitoring goals, identify potential regulatory issues resulting from monitoring, and develop an appropriate monitoring program for the watershed.

- *Occurrence, fate, and transport of PPCPs in three drinking water sources in California* – This NWRI-sponsored study assesses the sources, fate, and transport of selected PPCPs in three major drinking water sources in California, providing water agencies with information on the impact of wastewater on drinking water supplies.
- *Effects of emerging contaminants on southern California flatfish: synthesis and next steps (SCCWRP)* – A comprehensive survey of CEC occurrence and endocrine disruption associated with POTW effluent, receiving seawater, sediments, and flatfish from the coastal ocean off southern California.

Along with numerous examples of other high-level guidance and quality research projects supported by government (e.g., National Research Council) and industry (e.g., Water Research Foundation, Water Environment Research Foundation, NWRI), these early efforts will collectively serve as the starting point for the process of developing a monitoring framework for California. Since many of the Workshop attendees are actively involved with these efforts, it would be prudent to utilize their knowledge and experience throughout the investigative monitoring program development phases. These steps will allow the full scope of science to be incorporated into designing and implementing CEC monitoring, and will also minimize the possibility of avoidable, yet costly omissions and/or unnecessary additions.

4.2 Chemical prioritization

4.2.1 Retain flexibility in approach

Once the CEC monitoring goals have been defined, chemical prioritization for monitoring can be accomplished using three primary approaches identified by Workshop participants: risk-based, occurrence-based, and modeling-based (**Fig. 3**). The use of each approach is dependent on the availability of occurrence and toxicity data, which may vary widely by chemical in terms of the amount and relevancy to monitoring goals. Because of this variation, and the fact that new scientific information is always becoming available, it is important to retain flexibility in the type of approach used during the prioritization process. Local and/or regional CEC usage information (where available) and expert judgment should be primary elements of all three approaches.

Risk-based approach

The risk-based approach for prioritization should be used when appropriate occurrence and toxicity data exist for the chemical of interest. When feasible, this approach is the most effective because it is based on empirical data rather than modeling data. Using this approach, exposure to wildlife and/or humans and associated impacts can be predicted based on actual concentrations in the environment and laboratory-based toxicity studies. Determination of the amount and type of data applicable for use with the risk-based approach will need to be determined by the data user, with input from experts highly recommended. The synthetic hormone 17α-ethynylestradiol (EE2) is an example of a chemical suitable for prioritization using the risk-based approach, since it is well-studied, frequently occurs in the environment, and has confirmed endocrine disruption potential (USEPA, 2008).

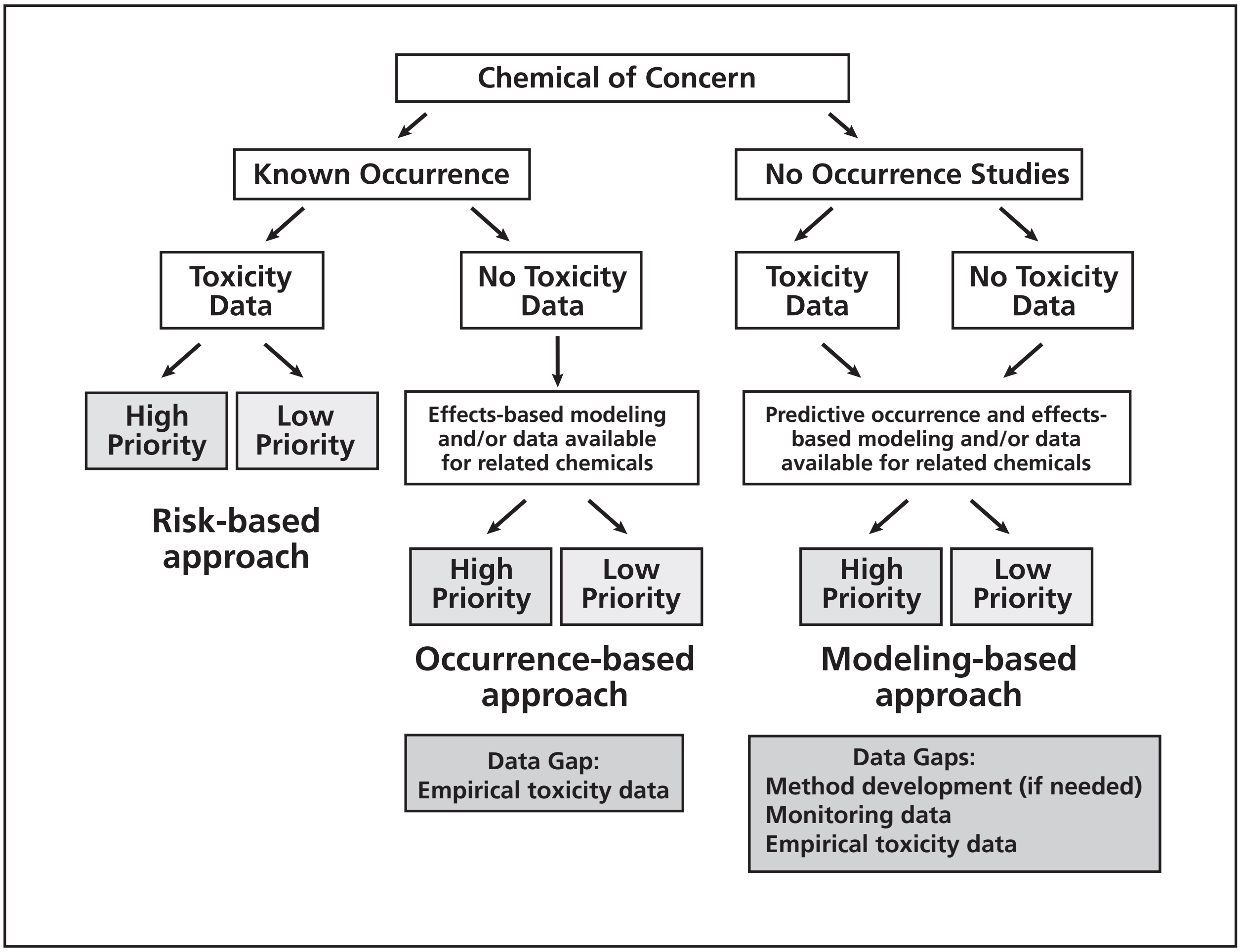

Figure 3. *Risk-, occurrence-, and modeling-based elements offer flexibility in prioritizing CECs based on the availability of information (e.g., occurrence and toxicological data) and measurement technology.*

Occurrence-based approach

The occurrence-based approach for prioritization should be used when appropriate occurrence data exist for the chemical of interest and when toxicity data are lacking. Using this approach, exposure to wildlife and/or humans can be predicted based on actual concentrations in the environment; however, associated impacts of the chemical on human and/or ecological health must be predicted based on effects-based modeling. If the risk-based approach cannot be used due to lack of toxicity data, the occurrence-based approach is preferred over the modeling-based approach because it includes some empirical data rather than all modeling data. The decision to use the occurrence-based approach may trigger the need for experimental toxicity data and/or more occurrence data relevant to the monitoring goals. PBDE flame retardants and the anticonvulsant drug carbamazepine are examples of chemicals that may be appropriate for prioritization using the occurrence-based approach for assessing ecological health. PBDEs are ubiquitous in all environmental matrices, and carbamazepine is frequently detected in finished drinking water, as well as fresh and marine ambient waters (Benotti et al., 2009; Guo and Krasner, 2009; Bay, 2008). In addition, while much may be known regarding potential human health impacts, very little is known regarding potential ecological impacts (toxicity).

Modeling-based approach

The modeling-based approach for prioritization should be used when neither appropriate occurrence nor toxicity data exist for the chemical(s) of interest. Using this approach, quantitative structure-activity relationships (QSARs) and known physico-chemical parameters, such as half-life, vapor pressure, bioaccumulation factors, and octanol-water partition coefficient, can be used to predict the fate, transport, and bioaccumulation potential of a particular chemical. QSARs and other types of effects-based modeling (e.g., high throughput screening and ToxCast; USEPA, 2009) can also be used to predict the potential toxicity of a chemical to various receptors, including humans. In addition, these tools may offer the best chance for assessing the effects of chemical mixtures that are found in the environment. The modeling-based approach is the least preferred approach because it is minimally, or not at all based on empirical data. The decision to use this approach may trigger the need for monitoring data in the system of concern and/or experimental toxicity data relevant to the monitoring goals, so that an occurrence- and/or risk-based approach can be subsequently used to prioritize the chemical. Chemicals that may be appropriate for prioritization using the modeling-based approach include many of the persistent, bioaccumulative, and toxic substances recommended for environmental monitoring by Muir and Howard (2007). For many of these chemicals, virtually no information is available on their occurrence and toxicity, and no analytical methods have been developed, despite the high-volume use of these chemicals.

4.2.2 Prioritize CECs by monitoring application

Because of the diversity, number and potential geographical differences in monitoring applications (Section 3.1 *Define the applications for monitoring*), a single "master" list of priority CECs will not address all defined monitoring goals. It is likely that constituents of concern will depend on a number of application-specific primary factors, for example:

- Type/nature of water, waterbody, or waste stream (e.g., drinking water, recycled water for indirect potable reuse, ocean discharge, stormwater runoff).
- Degree of treatment afforded to water/waste stream prior to application/discharge.
- Impact of concern (e.g., human vs. ecological health).
- Geography and land use (e.g., urban vs. agricultural).

The possible combinations of these primary factors for waste streams and ambient receiving waters are many within a state as large and as geographically diverse as California. For example, different high priority CECs for the various monitoring applications may be proposed, resulting in several preliminary lists. Although a given high priority CEC may "crossover" into two or more applications, the composite list of CECs for each application will differ based on the beneficial use of concern (ecological vs. human health), the endpoint of concern (e.g., cancer vs. reproductive dysfunction), and the level of treatment received by each water system. Land use and geographic specificity will also play a role in selecting priority CECs for monitoring. For example, PPCPs are typically associated with urban and/or suburban landscapes, whereas pesticides (e.g., atrazine, diuron, and simazine) may be used largely in agricultural areas. Upon further review of these applications and as additional preliminary monitoring data becomes available, it may prove beneficial to collapse these numerous combinations into a smaller, more manageable number that can be applied statewide.

4.2.3 Use indicators and surrogates to reduce complexity/cost

To enhance the effectiveness and vastly reduce the complexity and potential cost associated with monitoring hundreds of CECs, the use of indicator compounds and surrogate parameters has been proposed. In many instances, measuring indicators and surrogates is the only viable alternative for CECs for which no analytical methods currently exist. Indicators are specific compounds that behave similarly to actual target CECs in terms of their fate in complex treatment or natural systems. For example, the anxiolytic meprobamate can serve as an indicator of pharmaceuticals in the waste stream that survive conventional (i.e., primary and secondary) wastewater treatment processes. Surrogates are quantifiable parameters that correlate with specific CECs and, as a result, indicate a level of treatment or removal within a system. Examples of possible surrogates are ultraviolet absorbance (UVA), total organic carbon (TOC), and oxidation byproduct formation.

Several recent studies have illustrated the potential benefits of indicators and surrogates for monitoring of CECs, mostly for highly treated wastewater, recycled water, or drinking water applications. The best choice of indicators and surrogates will depend, once again, on the application and, at the next level of specificity, the degree and nature of treatment and/or natural attenuation expected in the system of interest. In a recent study on advanced oxidation processes for recycled water, for example, several PPCPs including dilantin, *N,N*-diethyl-meta-toluamide (DEET), meprobamate, and iopromide were identified as potential indicators, whereas UVA and organic acid formation showed promise as surrogates (Dickenson et al., 2009). For source and drinking water subject to different levels of polishing treatment, atenolol, atrazine, DEET, estrone and meprobamate were identified as potential indicators (Benotti et al., 2009). In a study on the discharge of primary and secondary wastewater effluent via marine outfalls, indicators that are typically removed by advanced water or wastewater treatment processes such as carbamazepine, gemfibrozil, and naproxen may be best suited for these specific applications (Bay, 2008). Caution should be exercised when comparing recommendations for indicators and surrogates as analyte lists may vary across such studies.

4.3 Tiered water quality thresholds

4.3.1 Select the right combination of analytical tools

The status quo for regulatory monitoring of chemicals of concern is to measure their environmental concentrations individually using an analytical method that involves chemical instrumentation, or a combination of physical, chemical, and biological measurement techniques. This straightforward strategy has been in use since the advent of environmental regulations in the 1970s. "Chemical-specific" measurements are typically processed and analyzed for comparison with set threshold or regulatory levels; if measured levels approach or exceed set thresholds, then an appropriate management action is warranted.

Currently, low-level analytical methods (i.e., at parts per trillion or below) are available for many CECs that are able to produce much of the information needed for management decision making. Benotti et al. (2009) and EPA Method 1694 (USEPA, 2007) describe methods that incorporate current instrumental technology (i.e., LC/MS/MS) to measure dozens to hundreds of CECs (mostly PPCPs) in environmental matrices of concern (e.g., drinking water) at or in some cases well below levels that may be relevant based on known toxicological information. Other adaptations of procedures first published by researchers are also available in the peer-reviewed literature. These provide additional opportunities to augment and build a repertoire of robust analytical tools, however, the Workshop participants were quick to point out that such low-level methods may not be warranted in all cases, where in fact more conventional and cost-effective techniques may suffice. As high priority CECs are identified, adaptation, development, and validation of robust chemical analytical methods to measure these constituents with an appropriate degree of sensitivity will continue to be a necessity.

Chemical-specific analytical methods, however, are limited in application, as they quantify exposure or, in most cases, exposure potential, and are manageable and cost-effective only for a relatively small number of CECs. *In vitro* bioanalytical techniques, including immunoassays and genomics-based assays that measure responses linked to deleterious biological or ecological impacts, may be an attractive supplemental or alternative technique for monitoring of CECs. Because these methods can be tailored for specific responses, they can serve to quantify the cumulative action of a class or mixtures of several classes of CECs that elicit responses in a specific toxicity pathway. Some examples of bioanalytical tools that have been used or that are currently being developed include:

- Gene microarrays to develop bioactivity signatures that are linked to impacts such as cancer, reproductive effects, and neurotoxicity (e.g., gene regulation of steroid hormone production).
- Proteomics (e.g., analysis of vitellogenin, an egg yolk precursor protein that indicates feminization of male fish exposed to endocrine disrupting chemicals).

In vitro methods allow a much more efficient screening process for CECs compared with current *in vivo* animal methods (USEPA, 2009). There is a potential need to develop and test such tools to provide a stronger linkage to mode of action and, ultimately, to impacts of concern for specific freshwater and marine targets (i.e., sentinel species, populations, or communities).

4.3.2 Establish response-appropriate thresholds

Health- or effects-based thresholds (i.e., thresholds of toxicological concern) are used to inform regulatory decision-making and, if necessary, to initiate appropriate management actions. With sufficient knowledge, thresholds may be applied singularly (e.g., in establishing water quality criteria or objectives). Because of the high degree of uncertainty associated with most CECs, the Workshop participants felt that actions taken based on exceedance of single thresholds or “bright lines” can result in unsatisfactory outcomes, particularly when concentrations of interest occur near the bright line. To better inform decision making and provide early warning for new CECs, a proactive strategy that utilizes response-appropriate monitoring measurements within a tiered, multiple threshold interpretive framework was recommended. This framework should inform management responses and/or actions, if necessary, that are appropriate with the level or “tier” of occurrence or exceedance.

Developing credible effects levels is the first step in defining management level thresholds for the interpretive process. Existing frameworks and studies generated by the USEPA (e.g., CCL3) and the USFDA, as well as industry risk assessments and databases such as those published by the WateReuse Foundation, Water Research Foundation, Water Environment Research Foundation, NWRI, and others can be used to develop thresholds for many CECs. These tools are particularly applicable for those CECs that are known or suspected of being carcinogenic or teratogenic. For CECs that do not fit into existing risk assessment paradigms (i.e., those for which cancer is not the most relevant impact), a general conceptual model that defines mode of action and receptor organisms of concern can be used (**Fig. 4**). After these parameters have been identified, data from the literature can be compiled and a number of effects levels based on no, minimal, or probable effects levels can be determined statistically, using currently employed or proposed approaches.

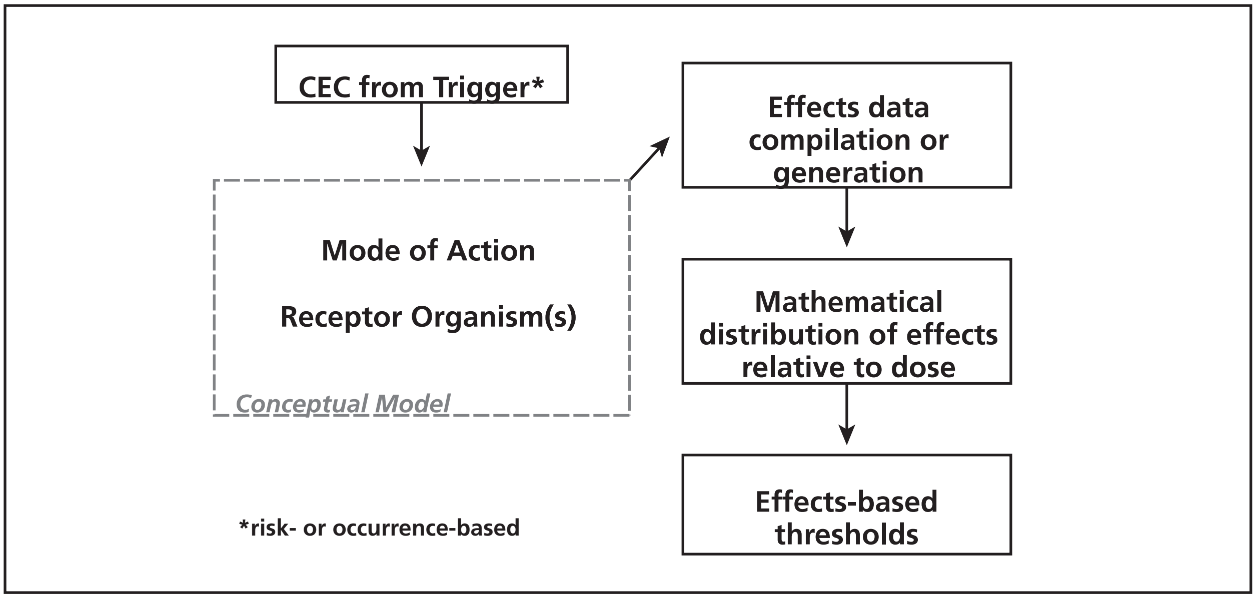

Figure 4. *Establishing effects-based thresholds should consider the toxicological mode(s) of action for CECs and receptor organisms that are relevant to the monitoring application.*

Once effects levels have been determined, a final interpretive step is needed to determine what, if anything, to do next. In the face of high potential uncertainty associated with new information, a tiered, multiple threshold structure, in which the level and aggressiveness of management response/action is dependent on the severity of threshold exceedances, would provide "buffering" from uncertainty and minimize chances for grossly inappropriate, ineffective, or unwarranted responses. For example, monitoring data that consistently indicates levels of a target CEC to be at or below levels for which little or no impact is to be expected would be met with little response (Tier I in **Fig. 5**). If this condition exists for a prolonged time period, the Tier I condition could result in removal of the CEC from high priority status. Conversely, a target CEC that consistently (or intermittently) exceeds thresholds associated with probable or definite impacts would initiate multiple and more urgent management responses, including but not limited to implementation of best control/management practices (Tier IV). Monitoring data that falls in between the two extremes could trigger an intermediate level of response (e.g., additional monitoring effort, refined risk assessment and studies to elucidate sources with the intention of eliminating and/or minimizing their input, and/or more studies to refine effects [Tiers II and III]). Whereas this example illustrates the tiered threshold concept, the Workshop participants did not discuss in detail the number and gradation of tiering levels, nor did they endorse a specific tiered structure. Additional collaboration is needed to refine this conceptual approach, particularly as more data for individual chemicals regarding their mode of action and expected effects become available.

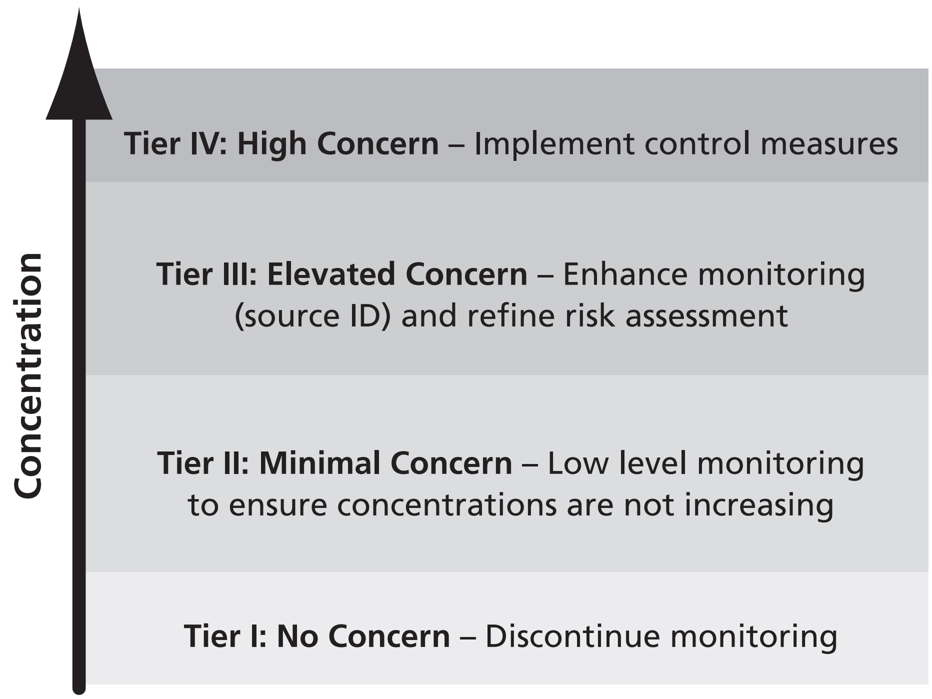

Figure 5. *Multiple thresholds representing various levels of risk or effect are tied to appropriate management actions in a tiered interpretive framework.*

5. CHALLENGES FOR IMPLEMENTATION

Summary of Workshop findings:

- Risk communication plans are needed and should be tailored to audiences for each monitoring application.
- Opportunities for stakeholder input, frequent and clear public communication, and timely response to new information are key elements in a CEC management approach.
- Agencies with common goals should work together to prioritize issues, leverage resources, and engage in collaborative regional monitoring programs.
- Because the state of knowledge surrounding CECs is constantly in flux, the process for CEC monitoring and management should be amenable to change.

5.1 Effective communication is key

Workshop participants emphasized the need for a CEC communication strategy to enhance understanding of management activities in light of the many uncertainties. Several such plans, tailored to distinct consumers and/or audiences, may be needed to address specific monitoring applications. Key elements of these plans include:

- A clear statement of monitoring goals – investigative vs. regulatory.
- The process for selecting high priority constituents – occurrence-, risk-, or modeling-based prioritization.
- Key knowledge gaps and what is being done to fill them.
- Appropriate uses of data.
- Coordination and collaboration among stakeholders.
- Public participation (e.g., voluntary risk reduction programs).
- Identifying the most effective media outlets (websites, pamphlets, town hall meetings).

Effective communication among scientists/engineers, stakeholders, and the public will be vital to effective management of CECs. To foster collaboration and trust within stakeholder communities, the *process* behind setting goals and developing designs for CEC monitoring must be a transparent one. A commitment to sustain collaboration from all stakeholders is one of the most important steps toward maximizing transparency. An important part of establishing trust is defining appropriate and inappropriate uses of monitoring data, particularly if the goal for collecting such data is not compliance-based. In these instances, pilot or investigative monitoring studies usually carry higher levels of uncertainty due to limited sampling effort and the use of untried or partially validated methods along with non-regulatory data interpretation methods. Data from pilot studies should be embraced by regulators and dischargers alike, without fear of misuse or misinterpretation. Regular exchange among stakeholders would help define appropriate data uses, while at the same time facilitating and increasing data sharing.

To develop public trust, the purposes of monitoring must be clearly stated and communicated. Differentiation between occurrence (particularly at very low levels made possible by advancing technology) and impact or effect needs to be made. The rationale, definitions, and implications associated with the tiered, multiple threshold interpretive framework (Section 4.3.2 *Establish response-appropriate thresholds*) should be expressed in the simplest terms possible. Risk from consuming CECs in drinking water or in seafood needs to be put in perspective, for example, by comparison to risks associated with other daily life activities. Explanations of how treatment plants do or do not remove a given (class of) CEC should be part of an integrated effort to communicate with and educate the public.

Timely response to new findings goes a long way in solidifying trust among all parties involved. A large part of responding to new data is anticipating their impact based on other studies and knowledge gained from other research and management communities. Periodic interchanges among the research and stakeholder communities are one way to ensure knowledge is current and widespread. Easily updated media outlets (e.g., monthly bulletins, webpages) should be used to communicate these updates between scheduled meetings/workshops.

5.2 Develop and channel resources

The sheer number of CECs and large data gaps present a potentially expensive challenge for water resource managers. The USEPA has estimated funding levels of $100 million per year for the next decade are needed to develop a new risk assessment paradigm for CECs at the federal level (USEPA, 2009). With monitoring of currently regulated contaminants already on the books, there are limited resources available to deal with this complex issue. Thus, it is crucial that investments to manage CECs for the protection of human and environmental health in California be well spent. Several opportunities were identified by Workshop attendees to develop funding support and to maximize the benefit of dollars committed to CEC monitoring and research, including:

- Understand, document, and prioritize data/knowledge gaps.
- Prioritize monitoring goals.
- Pursue cooperative studies (i.e., increase and take advantage of collaboration).
- Promote regional-scale monitoring.

A number of cooperative studies have been initiated (Section 4.1 *Don't re-invent the wheel*), with the results of these efforts included as Workshop background material. Invariably, these studies have brought together experts in various disciplines to address the most pressing management questions, including many of those identified earlier as priority monitoring goals (Section 3.2 *Establish monitoring goals to protect beneficial uses*). Regional studies have been especially successful in leveraging local resources to answer questions at a larger geographic scale (e.g., how pervasive are CECs?). Within California, dozens of local and regional agencies band together to perform comprehensive environmental quality studies on the Southern California Bight (performed once every five years at several hundred sites) and San Francisco Bay (performed annually at a smaller number of sites). At the national level, the National Oceanic and Atmospheric Administration (NOAA) National Status and Trends Program and the United States Geological Survey (USGS) National Reconnaissance efforts leverage regional and state resources in expanding geographic coverage, the number of environmental matrices monitored (e.g., water, sediment and tissue), and analytical capability, resulting in a larger list of target analytes.

Understanding key data gaps will help prioritize their importance for the research community, as well as for the agencies that provide funding for CEC research. Delineating the priority research areas for funding agencies, such as the WateReuse Foundation, Water Research Foundation, WERF, NWRI, and USEPA, will maximize the relevance of their CEC research agendas. Future research agendas may include filling the following data gaps:

- CEC production volumes.
- Conceptual life cycle models.
- Trophic transfer.
- Fate and effects of CEC metabolites and conjugates.
- Low-level effects (molecular, organism, population level).
- Effects of exposure to chemical mixtures.

5.3 Adapt to the moving target

A key element of this process will be our ability to adapt the strategy as new information becomes available. Since relatively little is known about CECs at this time, new information and technology will undoubtedly affect our ability to monitor and establish thresholds for CECs. Preliminary CEC monitoring lists will be subject to trial and error. Future advances in treatment technology and/or changes in chemical use will clearly affect the loading potential, and thus occurrence, for certain CECs. Therefore, the process that we follow to manage CECs must also be able to adapt to this new information. Inclusion and subsequent interpretation of investigative monitoring data will likely result in changes to the preliminary lists of high priority CECs. For example, some initial candidates may be de-emphasized while other newly identified CECs may be added.

For prioritization, the risk-, occurrence- and modeling-based elements (**Fig. 3**) must be able to assimilate new or higher quality information and/or methods. Seamless incorporation of new toxicological information, such as those identifying new modes of action or additional toxicity pathways for newly detected CECs, should be a key feature of the appropriate prioritization elements. The framework must also allow for incorporation of additional monitoring data that can influence the magnitude of uncertainty associated with effects levels and thus thresholds.

Lists of CECs by monitoring application and prioritization frameworks will need to be periodically revisited by experts in the field to ensure their current relevance. This will also be prudent for analytical monitoring tools, for which technology is rapidly evolving. Improved science, whether it takes the form of more accurate predictive models, enhanced monitoring data, or a more comprehensive set of toxicological information, must be incorporated at regular intervals throughout the process.

6. NEXT STEPS

Summary of Workshop findings:

- Develop preliminary CEC monitoring lists by application.
- Identify measurement techniques for preliminary constituents that meet monitoring goals.
- Incorporate preliminary lists and methods into existing/future regional studies.

Because we are in the early stages of developing a CEC monitoring strategy, filling the data gaps identified in this and other workshops is clearly the first step. This can be accomplished through investigative monitoring and targeted research. To address questions on occurrence, we must first develop preliminary monitoring lists of CECs for applications with the highest potential for significant impact, as well as those that are mandated by State policy (e.g., for recycled water) and that best serve public interests (e.g., drinking water supplies). In conjunction with the latest research findings, the process described herein can serve as the basis for selecting a "proposed list" of CECs and identifying those indicators/surrogates that are most applicable for these specific monitoring applications.

The second step will be to identify and, as necessary, develop and test the most appropriate monitoring methods for these proposed constituents, including those based on novel biological endpoints or techniques. Selection of these methods should be based on a thorough examination of monitoring goals, including appropriate limits of detection, precision, and accuracy. Laboratory intercalibration exercises will be a key component in determining which methods show promise for test or pilot investigations, and eventually for widespread use and adoption by monitoring agencies.

The third step will be to incorporate measurements of the proposed CECs into the design and implementation of existing and future planned studies, including:

- Local or regional water quality studies.
- Local or regional drinking water supply studies.
- Local or regional recycled or reclaimed water studies.
- NOAA's National Status and Trends Mussel Watch Program.
- San Francisco Estuary Regional Monitoring Program.
- Southern California Bight Regional Survey (coastal and marine).

As part of this step, it will be necessary to establish a second level of monitoring design parameters, such as matrices to be analyzed, frequency and timing of sample collection, and spatial/geographical coverage of the monitoring efforts. Recommendations for the secondary design parameters will come from previous studies and from the latest peer-reviewed literature.

These collaborative, investigative "pilot" studies will be key in refining the preliminary CEC monitoring lists, as testbeds for developing and transferring new technology/methods, and in communicating and sharing new information among diverse stakeholder groups. In addition, the Workshop Organizing Committee will actively provide input and important study findings to partner agencies, such as the WateReuse Foundation, Water Research Foundation, NWRI, Water Environment Research Foundation, and others that fund CEC research.

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Appendix A – Workshop Goals and Agenda

Managing Contaminants of Emerging Concern in California: A Workshop to Develop Processes for Prioritizing, Monitoring, and Determining Thresholds of Concern

April 28-29, 2009
Southern California Coastal Water Research Project
Costa Mesa, CA

Sponsors

California Ocean Protection Council
California Ocean Science Trust
National Water Research Institute (NWRI)
University of California Irvine, Urban Water Research Center (UWRC)
San Francisco Estuary Institute (SFEI)
Southern California Coastal Water Research Project (SCCWRP)

Organizing Committee

Amber Mace (California Ocean Protection Council)
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Stephen Weisberg, Keith Maruya, Steven Bay (SCCWRP)
Jonathon Bishop (State Water Resources Control Board)
Suzanne Rudzinski (USEPA)
Deborah Smith (Los Angeles Regional Water Quality Control Board)

Background

Contaminants of emerging concern (CECs) are a diverse group of relatively unmonitored and/or unregulated chemicals that have potential for deleterious human health effects in drinking water and ecological effects in fresh and marine ambient waters. These chemicals include pharmaceuticals, personal care products, and other trace organic chemicals. Some of these contaminants have been shown, or are believed, to affect endocrine systems. Scientists are generating a substantial amount of information to quantify the presence and assess the potential human and ecological health impacts of CECs. There have been a number of workshops where scientists have had the opportunity share results among themselves and chart future directions for their scientific investigations.

State and local health and regulatory agencies are aware of, and in some cases are funding, this research, but have not yet synthesized the information into a comprehensive strategy for developing their monitoring and regulatory actions. The purpose of this workshop is to provide a forum for the sponsoring organizations to engage the scientific and research community to provide input and priorities for helping determine regulatory directions, including support for:

- State Water Resource Control Board's proposed Blue Ribbon Panel on CECs as described in the State Water Recycling Policy
- California Ocean Protection Council's understanding of CECs as they relate to managing coastal resources
- California Department of Public Health and Regional Water Quality Control Board's permitting activities related to CECs
- Other local and state regulatory activities

Workshop Goals

The Workshop will delineate processes that the State should employ to:

1. Identify which CECs are of sufficient concern to be incorporated into routine aquatic monitoring programs.

2. Standardize the measurement processes and techniques that will be used for monitoring priority CECs.

3. Determine thresholds of ecological and human health concern for interpreting CEC monitoring data.

Format

A panel of 50 scientists, regulators and water quality managers will be convened for a 2-day Workshop. Plenary presentations to open the Workshop will summarize the state-of-the-science and inform participants on current State regulatory practices for waterborne contaminants and the water quality challenges that unmonitored CECs present to management. After the plenary talks, Workshop organizers will charge participants in three sequential sessions addressing Goals (1) – (3), with breakout groups organized to encourage input and participation. The Workshop will conclude with a summary of the processes identified to guide the future actions of State, regional and local water quality managers.

Products

A written report summarizing the goals, findings and attendee information for the Workshop will be made available to all participants and interested parties. The report will be targeted to a management audience and will highlight the practical aspects of the Workshop findings.

As the workshop is being conducted to meet information needs expressed by multiple governing bodies (see Background), including the California State Water Resources Control Board and the California Ocean Protection Council, oral presentations of key Workshop findings will be made to these entities.

Managing Contaminants of Emerging Concern in California: A Workshop to Develop Processes for Prioritizing, Monitoring, and Determining Thresholds of Concern

Meeting Agenda
April 28-29, 2009

Meeting Location
Southern California Coastal Water Research Project
Main Conference Room
3535 Harbor Blvd., Suite 110
Costa Mesa, CA 92626
Phone: (714) 755-3200

Tuesday – April 28, 2009

8:00 am	**Registration and Refreshments**	
8:30 am	**Welcome, Introductions, and Goals for the Workshop**	Steve Weisberg, SCCWRP
8:40 am	**Regulatory Perspective** - CA State Water Resources Control Board - CA Department of Toxic Substances Control - U.S. Environmental Protection Agency - Santa Ana Region "Emerging Contaminants Task Force" Case Study	Steve Weisberg, Moderator - Tam Dudoc (SWRCB) - Maziar Movassaghi (DTSC) - Suzanne Rudzinski (EPA) - Tim Moore (Risk Sciences)
10:00 am	BREAK	
10:20 am	**State of the Science** Occurrence and Fate of CECs Human Health Effects Ecological Effects Prioritization Frameworks	Bill Cooper, UCI, Moderator - Shane Snyder (SNWA) - Joyce Donahue (EPA) - Dan Schlenk (UCR) - Derek Muir (Env. Canada)
11:50 am	**Charge to Participants**	Steve Weisberg
Noon	**LUNCH**	**Patio**
1:00 pm	**Breakout Session I:** Identifying priority CECs for regulatory monitoring	Breakout Groups
3:50 pm	**BREAK**	
4:10 pm	**Plenary Session:** Group reports from Session I and Synthesis of Day's Activities	Steve Weisberg (Moderator) and Participants

5:15 pm	**Adjourn**	
6:00 pm	**DINNER**	**The Golden Truffle** 1767 Newport Blvd Costa Mesa, CA 92627 (949) 645-9970

Wednesday – April 29, 2009

8:00 am	**Refreshments**	
8:30 am	**Breakout Session II:** Developing the appropriate monitoring program for regulatory decision making	Breakout Groups
10:50 am	**Break**	
11:10 am	**Plenary Session:** Group reports from Session II	Steve Weisberg (Moderator) and Participants
Noon	**Lunch**	**Patio**
1:00 pm	**Breakout Session III:** Establishing water quality thresholds	Breakout Groups
3:50 pm	**Break**	
4:10	**Plenary Session:** Group reports from Session III, Synthesis and Workshop Summary	Steve Weisberg (Moderator) and Participants
5:15	**Adjourn**	

Managing Contaminants of Emerging Concern in California: A Workshop to Develop Processes for Prioritizing, Monitoring, and Determining Thresholds of Concern

Breakout Sessions

Breakout Session I – Identifying priority CECs for regulatory monitoring

April 28, 2009 (1:00 to 3:50 pm)

Four breakout groups, two each for ecosystem and human health and each composed of a mix of scientists, regulators and managers, will address the same charge questions.

Primary Question: What process and criteria should be used for the identification and prioritization of CECs to be monitored for regulatory purposes?

Desired outcome:

- **Framework(s) for the process of identifying and prioritizing CECs for monitoring, including list(s) of criteria used.**

Secondary Question 1. Are different approaches needed to address freshwater/marine ecosystems and human health?

Desired outcomes:

- A recommendation on whether different approaches are needed
- A list of advantages and disadvantages associated with this decision

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Secondary Question 2. Are different approaches needed for addressing different classes of CECs (e.g., pesticides, pharmaceuticals, nanoparticles)?

Desired outcomes:

- A recommendation on whether different approaches are needed
- A list of advantages and disadvantages associated with this decision

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Secondary Question 3. Are there CECs that should already be excluded/included in monitoring programs without further analysis?

Desired outcome:

- A list of CECs to exclude and/or include in routine monitoring programs based on currently available information

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Secondary Question 4. What information gaps exist and how do we fill them? Please see examples of existing information sources in the background material provided.

Desired outcome:

- A list of primary information sources, gaps and strategies to fill knowledge voids

Breakout Session II – Developing the appropriate monitoring program for regulatory decision making

April 29, 2009 (8:30 to 10:50 am)

Four breakout groups, two each for ecosystem and human health each with a mix of scientists, regulators and managers, will address the same charge questions.

Primary Question: What is the appropriate <u>design</u> for a CECs monitoring program to support water quality management?

<u>Desired outcome</u>:

- **A list of specific goals that can be expected to be addressed by a model monitoring program**
- **A framework for a model monitoring program that includes methods**

Secondary Question 1. What are the appropriate parameters for CECs (e.g. total vs. dissolved)? What matrices should be targeted? Is the list of priority CECs matrix dependent? How often should we monitor? Where?

<u>Desired outcome:</u>

- List of recommended parameters, matrices, frequency and locations to monitor

Secondary Question 2. What criteria should be used to <u>select</u> candidate analytical methods? What minimum validation criteria should be required to standardize methods for use within California?

<u>Desired outcomes</u>:

- A list of standardized methods ready for inclusion (e.g. EPA standard methods)
- A list of minimum criteria needed for validation of non-standardized analytical methods

Secondary Question 3. What process would facilitate the <u>development</u> of analytical methods for priority CECs for which no methods exist?

<u>Desired outcome</u>:

- A recommended framework for facilitating the analytical method development process

Secondary Question 4. What non-traditional techniques and/or ecological/human health endpoints and/or exposure indicators (e.g. biomarkers) should be considered? What process could be used to develop and validate these techniques?

<u>Desired outcomes:</u>

- A list of recommended non-traditional endpoints and techniques
- A framework for validating, implementing and incorporating non-traditional techniques into regulatory monitoring programs

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Breakout Session III – Establishing water quality thresholds

April 29, 2009 (1:00 to 3:50 pm)

Four breakout groups, two each for ecosystem and human health each with a mix of scientists, regulators and managers, will address the same charge questions.

Primary Question: What <u>process</u> should be used for establishing water quality thresholds for priority CECs?

<u>Desired outcome</u>:

- **Framework(s) for the process of establishing water quality thresholds for priority CECs for monitoring, including list(s) of criteria and tools used**

Secondary Question 1. How do we determine impairments in water, sediment, and biota? What are the assessment tools that will be used to link chemical concentration to biological endpoints of regulatory concern? If not available, how do we develop these tools for CECs?

<u>Desired outcomes:</u>

- A list of recommended assessment tools
- A framework for developing and implementing the use of these tools

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Secondary Question 2. What is the appropriate degree of specificity for establishing thresholds – i.e. should they apply universally for all waters or be established based upon beneficial use and/or environment (e.g. ambient freshwater vs. marine; potable vs. treated wastewater)? Should a tiered approach be used (e.g., highest tier protection of human health drinking water sources, lower tier discharge of wastewater to nonpotable sources.)?

<u>Desired outcome:</u> Recommendations of the appropriate spatial and temporal scales for developing thresholds.

Secondary Question 3. What are the appropriate spatial (e.g. statewide vs. site specific) and temporal scales for developing thresholds?

<u>Desired outcome:</u> Recommendations of the appropriate spatial and temporal scales for developing thresholds.

Secondary Question 4. How should uncertainty be incorporated into an assessment framework?

<u>Desired outcome:</u> Recommendations for incorporating uncertainty analysis into an assessment framework.

Appendix B – Workshop Participants

Managing Contaminants of Emerging Concern in California:
A Workshop to Develop Processes for Prioritizing, Monitoring, and Determining Thresholds of Concern
April 28-29, 2009

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