Tri-TAC
Jointly Sponsored by:
League of California Cities
California Association of Sanitation Agencies
California Water Environment Association

March 19, 2012

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Via Electronic Mail & U.S. Mail
Dr. Keith Maruya and Panel Members
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Subject: Comment Letter – February 22, 2012 Draft Monitoring Strategies for Chemicals of Emerging Concern (CECs) in California's Aquatic Ecosystems: Recommendations of a Science Advisory Panel

Dear Dr. Maruya and Panel Members:

The California Association of Sanitation Agencies (CASA) and Tri-TAC are pleased to submit comments on the February 22, 2012 *Draft Monitoring Strategies for Chemicals of Emerging Concern (CECs) in California's Aquatic Ecosystems: Recommendations of a Science Advisory Panel* (draft report). CASA and Tri-TAC are statewide organizations comprised of members from public agencies and other professionals responsible for wastewater treatment. Tri-TAC is sponsored jointly by CASA, the California Water Environment Association, and the League of California Cities. The constituency base for CASA and Tri-TAC collects, treats and reclaims more than two billion gallons of wastewater each day and serves most of the sewered population of California.

The draft report is well written, and understandable considering the technical and scientific information presented to develop strategies for monitoring for CECs. We particularly appreciate the acknowledgement that, since information related to CECs in the aquatic environment is rapidly developing, it is appropriate to not only conduct monitoring for CECs but to also continue to advance the science behind potential CEC impacts in aquatic ecosystems. The monitoring strategy was appropriately developed using a risk-based framework so that monitoring would be focused on CECs posing the greatest potential risk.

While we are supportive of the overall approach adopted by the Panel as well as many aspects of the draft report, we do have some specific concerns. General comments relating to areas of support and areas of concern are provided below. Additional detailed technical comments are provided in Attachment 1.

- The draft report issued by the Science Advisory Panel for CECs in California's Aquatic Ecosystems (Panel) is informative and addresses issues associated with CECs in the State's aquatic systems. We support the Panel's conceptual, risk-based approach to assess and identify CECs for monitoring in California receiving waters, and their risk-based method for identifying a list of CECs for initial monitoring. Both approach and method are technically-based.

- The State Water Resources Control Board (State Water Board) convened the Panel to provide unbiased, science-based recommendations for monitoring of chemicals of emerging concern. Beyond identifying an initial list of CEC's to monitor, the Panel has brought forth a risk-based screening framework. In the event that other additional CECs are brought to the State Water Board's attention for listing, we believe that any recommendation for additional CEC monitoring undergo the same risk-based screening framework as outlined in this draft report. After the risk-based screening is complete, the same or similar unbiased Panel should determine the technical relevance for listing.

- It is important that any changes made to the plan are based on sound science and unbiased technical expertise. Therefore, we agree with the Panel that it is important that the Panel be reconvened to review results and make recommendations and adjustments, on an as needed basis, but at a minimum of every five years. We appreciate the open process the Panel has used to develop these monitoring strategies, and believe it is important that this continue to be an open process.

- The Panel provided four products intended to assist the State Water Board in developing a monitoring strategy for CECs. In particular, the third product defines an adaptive, phased monitoring approach with interpretive guidelines. We support the Panel's approach, but would ask that the State Water Board consider a cost assessment, resource assessment, and funding mechanism be defined prior to implementation of the monitoring approach, taking into consideration the limited resources from rate payers of impacted wastewater treatment plants and stormwater agencies.

- The fourth product defines research needs to develop bioanalytical screening methods, link molecular responses with higher order effects, and fill key data gaps. We commend the panel on establishing a path forward to bridge data gaps using future research. We also wish to emphasize the Panel's point that we are in the research phase of understanding risks posed by CECs. We ask both the Panel and the State Water Board to take into consideration this undefined risk and not place any undue burden on the agencies and their rate payers.

- Tri-TAC strongly supports the implementation of the Report's recommended monitoring programs through state-wide, regional, and local monitoring programs, rather than through individual monitoring requirements in National Pollutant Discharge Ellimination System (NPDES) permits. Requiring individual monitoring in all NPDES permits would consume resources that are better dedicated toward studies in the pilot areas proposed by the panel. The Panel should clearly state that it is not their intent for wastewater treatment plants (WWTPs) to be individually required to monitor for the list of "WWTP Effluent" compounds indicated in Table 8.1.

We urge the Panel and the State Water Board to wait until science supports any proposed regulation and if regulations are required, that it consider the relative potential of risk to balance available resources to mitigate the risk. Agencies are currently tasked with protecting public health and safety, and the environment, from known and quantifiable risks. Re-allocation of agency resources to monitor CECs will diminish the capacity to monitor known risks. We ask the Panel to consider additional research and funding mechanisms, such as the Water Environment Research Foundation and collaborative funding partnerships.

Our attached detailed comments identify some concerns and request clarification on a range of issues. We intend that these comments constructively contribute to recommendations resulting in a monitoring effort that will help inform the public, regulators and the water industry about this important issue.

Sincerely,

Roberta L. Larson
Director, Legal and Regulatory Affairs
CASA

Terrie Mitchell
Chair
Tri-TAC

RLL/mb
TM/mb

ATTACHMENT 1

Comments on February 22, 2012 Draft Monitoring Strategies for CECs in California's Aquatic Ecosystems: Recommendations of a Science Advisory Panel From CASA and Tri-TAC

March 19, 2012

General Comments

1. Because the report is expected be used to establish monitoring programs in permits, the report must provide clear direction for consideration by the State Water Board and California Department of Public Health (CDPH), and other regulatory agency staff.

2. Tri-TAC is fully supportive of a number of aspects of the Report, as listed below.

   - Use of a risk-based approach to prioritize compounds for monitoring.
   - Use of three different scenarios to develop a tailored monitoring approach for each scenario.
   - Approach used to identify antimicrobials/antibiotics for initial monitoring based on their concentrations relative to antibiotic resistance (ABR) thresholds.
   - Recommendation for an adaptive, phased monitoring approach. The four-phase monitoring approach that the Panel has outlined appears to be a sound, logical stepwise plan for selecting compounds of concern, developing appropriate validation and monitoring studies, and reassessing the approach every five years.
   - Recommendation to incorporate CEC monitoring into existing state-wide, regional and local monitoring program instead of requiring such monitoring at individual dischargers.
   - Consideration of monitoring approaches for antibiotics and antibiotic resistance. This is an issue of great importance in the clinical microbiology field but one that has, to date, received very little attention from an environmental health perspective.
   - Recommendation for the initial cycle of Phase 2 monitoring to be completed over a 5-year period, with the Panel reviewing the workplans before they are implemented.
   - Recommendations for specific monitoring to be conducted during Phase 2, including parameters, matrices, frequency, and locations.
   - Recommendation that monitoring recommended under Phase 2 not be used for compliance/regulatory purposes, but instead for investigation and potential additional follow-up actions.
   - Recommendation that, during Phase 3, Phase 2 results be evaluated within the context of a tiered risk-based monitoring and response framework.

- Inclusion of discussion of a broad range of available bioanalytical technologies, including important in vitro and in vivo bioassays as well as microarray technology and an approach for assessing antibiotic resistance.
- Recognition that the relevance and utility of *in vitro* bioassays is dependent upon linkages established to higher order effects such as survival, reproduction, development, and susceptibility to disease.
- Recognition that research is needed to determine adverse biological outcome pathways for CECs, to link *in vitro* bioassay results to higher order effects such as fish reproduction.
- Recognition that organisms may rapidly develop resistance to CECs (e.g., fipronil), so that multi-generational testing may be necessary to predict long-term chronic impacts.
- Recommendation that, if any CECs are found to be posing significant risks as part of the Phase 3 assessment, that an expert panel develop guidance on the development and assessment of specific action plans.
- Recommendation that the State compare the potential risks associated with CECs with the potential risks posted by other currently monitored environmental stressors to better direct future monitoring efforts.

Specific Comments

Executive Summary

These comments are offered in the context that most people who will read the final report will only read the Executive Summary. While many of the comments are addressed in the body of the report or in the appendices, some clarifications and/or elaboration in the Executive Summary may help avoid misunderstandings if this section is read as a standalone document.

3. Pg. iv, paragraph 1. "CECs with a hazard quotient (HQ=MEC (or PEC)/MTL) greater than "1" were identified for monitoring." Throughout the report, the term "hazard quotient" or HQ is used to indicate the ratio of the maximum/predicted environmental concentration (MEC/PEC) to the monitoring trigger level (MTL). In the scientific literature, the term "hazard quotient" is typically used to denote the ratio of occurrence to a "safe" concentration. Given the safety factors applied to develop monitoring trigger levels (MTLs), use of the term "hazard quotient" is not appropriate. NOECs/PNECs are derived to represent "safe" concentrations below which adverse effects are not expected to occur. In the Report, the Panel added a number of safety factors to the NOECs/PNECs to develop the MTLs. While is it is appropriate to include additional safety factors when developing monitoring recommendations, it is important that the MTLs not be construed as being the levels above which concentrations become "unsafe". In order to make it clear that the ratio of MEC/PEC to MTL is meant solely to determine whether monitoring should occur, the term "hazard quotient" should be replaced with a different term such as "monitoring trigger quotient".

4. Pg. iv, paragraph 3. "Priority was also given to CECs for which adequate quality assurance/quality control (QA/QC) information was available." Please identify CECs which the Panel recommends for monitoring in this document which did not have adequate QA/QC information.

5. Pg. v, paragraph 2. "For tissue monitoring, PBDEs 47 and 99 and PFOS, a perfluorinated chemical used in consumer product manufacture, were prioritized for monitoring." Please clarify that tissue monitoring applies to all dischargers including effluent dominated freshwater, coastal embayments, and offshore ocean discharge systems.

6. Pg. vii, paragraph 1. "The Panel urges the State to compare the potential risks associated with CECs with the potential risks posed by other, currently monitored environmental stressors." Can the potential risks posed by other stressors be evaluated using the same risk model? Can the Panel also include examples which apply this proposed risk–based framework to known stressors such as DDT, PCBs, or mercury to establish the relative risk-based tier of highly defined known knowns versus CEC's?

Chapter 1

7. Pg. 7, paragraph 2. The Report includes application of a number of safety factors to NOECs to derive monitoring trigger levels (MTLs). Tri-TAC is concerned that the MTLs developed in the report will be misinterpreted by regulators and/or the general public as levels above which CEC concentrations are considered unsafe. Among other things, it is possible that the MTLs will be misapplied as effluent discharge limits and/or thresholds to determine whether water bodies are impaired. As an example of misapplication of other thresholds that have been developed, the sediment quality guidelines called Effects Range Low (ERLs) have been used to set TMDL wasteload allocations in the Los Angeles Region, despite clear direction from the scientific community that this is not an appropriate use of the thresholds. Because of the high potential for misapplication of the MTLs, we believe that the Panel needs to use caution when applying safety factors to NOECs/PNECs to develop MTLs. Use of safety factors may be overprotective in general because laboratory tests are typically conducted using "ultra pure" (low DOC, low solids, etc.) water and using cultured, naïve (i.e., previously unexposed) organisms. Therefore, laboratory toxicity tests most often represent over-protective conditions that prevent and/or minimize the organism's adaptation and CEC attenuation expected in receiving waters. Second, the Report includes a safety factor of 10 for extrapolation of freshwater effects to saltwater. As the Panel notes in the Report (last sentence starting on page 20 and bottom of page 28), exposure/toxicity is typically reduced in saltwater due to lower solubility and temperature in saltwater environments. Given the conservative approach already taken regarding toxicity (e.g., using the lowest NOEC) and the other safety factors applied to many of these compounds, it does not seem scientifically justifiable to apply another safety factor to extrapolate from freshwater to saltwater fish. Third, in some cases the only toxicity information that is available relates to changes in physiology, tissue morphology, or biochemical function. In such cases, where there is uncertainty as to whether the measured effect is biologically

significant, the Panel should consider whether it is appropriate to apply safety factors and whether instead a 0.1 "biological relevancy" factor may instead be appropriate. Finally, the Panel should carefully review each individual safety factor to ensure it was appropriately applied. To provide transparency to the use of safety factors, a specific explanation regarding the application of each safety factor to each constituent should be added to Appendix D.

Chapter 2

8. Pg. 9, Box 2.1. Key Observations on Current Monitoring Efforts, last bullet. Could you explain what monitoring has been used to establish the scientific basis for setting thresholds and/or discontinuing monitoring? A specific example maybe helpful.

9. Pg. 13, Box 2.3. Regional, State and Federal Water Quality Monitoring Programs. The Sacramento Coordinated Monitoring Program (CMP) has been performing coordinated monitoring since 1991. CMP partnering agencies support many area programs committed to safeguarding river water quality in the Sacramento and American rivers. Data from the program is shared with a wide group of stakeholders that includes regulatory and other public agencies, nonprofit organizations, the general public, and private companies to enhance other environmental efforts in the region. (http://www.srcsd.com/cmp.php)

10. Pg. 15, paragraph 1, last sentence. Tri-TAC agrees with the Panel's recommendation that the State engage with national standard setting organizations to create certified and/or standard reference materials for analyzing for CECs in sediment and tissue matrices.

11. Pg. 15, paragraph 3. The use of time-of-flight (TOF) technology seems most appropriate for toxicity identification evaluation (TIE) purposes after a biological impact has been demonstrated. Simply screening environmental samples for new compounds, as recommended in the report, would only add to our existing toxicity data gaps and divert resources away from the development of the biological screening tools necessary to determine biological risk. It is recommended that the non-targeted analysis pilot evaluation studies be dropped, and replaced with studies to establish linkages between bioassays and biological effects of concern.

Chapter 3

12. Pg. 18, paragraph 2. "Although most CECs occur in trace concentrations (ug/L or lower) in WWTP effluent, the large volume (e.g. close to 1 billion gallons per day into the southern California Bight alone) discharged to receiving waters in California throughout the year can results in total mass loadings that are comparable to regulated environmental contaminants (e.g. heavy metals)." Can the Panel please elaborate and provide an example of this?

13. Pg. 18, paragraph 4. "Evaluation of discharge (controlled and/or incidental) from agricultural operations was not considered by the Panel." The Report indicates that agricultural operations were not considered by the Panel. This is a serious gap in the proposed monitoring program. The Report addresses both current use pesticides and

antibiotics/antibiotic resistant bacteria. Agricultural sources are known to be major contributors in these areas. Any CEC monitoring program that excludes agricultural sources will therefore be notably incomplete. The Panel should consider a scenario for waterways dominated by agricultural runoff. Please comment on why agricultural sources were not considered, especially when at least three of the CECs recommended for monitoring are pesticides used by agriculture.

14. Pg. 19, Box 3.1. Effects of conventional wastewater treatment on CEC concentrations in effluent, Tertiary treatment processes, first sentence – The first sentence contradicts a general statement made earlier that as wastewater treatment advances from primary, secondary, to tertiary more CECs are removed. This sentence says tertiary treatment processes are largely ineffective in attenuating CECs.

15. Pg. 22, Box 3.2. The last sentence of the "Effluent dominated freshwater systems in California" paragraph states that CECs derived from stormwater runoff may be relevant in effluent dominated freshwater systems. However, the Report does not mention dry weather runoff, which may form a significant fraction of the flows in effluent dominated freshwater systems during dry weather periods. Please comment on why dry weather runoff was not considered.

16. Pg. 23, paragraph 4. "Mid- and off-shore regions. Dilution factors for source inputs range from 44…" Should this lower range number be 27?

17. Pg. 23, footnote 10. "Initial dilution occurs as the buoyant discharge rises to the surface…" However, deep (>30 m) ocean discharges typically do not reach the surface but remain trapped below the pycnocline present during most of the year. It is suggested that "to" be changed to "towards" and that a statement be added about the discharges being trapped by the pycnocline before reaching the surface.

18. Page 24. Please clarify the difference between "rainfall" and "stormwater."

19. Pg. 24, paragraph 2. "Near-shore. Dilution factors were lowest for stormwater (5 to 71)" Should this read, "Dilution factors were lowest for WWTP and stormwater"?

20. Pg. 24, paragraph 3. "Precipitation. Dilution factors ranging from 200 to 26,000 were estimated for rainfall in all coastal regions." Please note that the Table 3.1 dilution factors for the Off- Shore Coastal Region (0-10 km) are an order of magnitude higher than the Near-Shore and Mid-Shore Coastal Regions. Is this what the Panel intended?

21. Pg. 27, paragraph 1. We do not agree that stormwater and other possible CEC sources (i.e., groundwater or atmosphere) have little influence on the loading and concentrations of CECs in the offshore environment, at least for CECs attached to particulates. As can be seen from satellite images, persistent turbidity plumes reach well offshore and may contribute to CEC loadings in shelf sediments. As such, particulate-associated CECs in stormwater should also be considered in this scenario.

Chapter 4

22. Pg. 29, paragraph 2. The Report indicates that in some cases the only toxicity information that is available relates to changes in physiology, tissue morphology, or biochemical function. In such cases, when there is uncertainty as to whether the measured effect is biologically significant, the Panel should consider applying a 0.1 times "biological relevancy" factor to be consistent with safety factors based upon uncertainty.

23. Pg. 29, paragraph 4, last sentence. Tri-TAC appreciates the Panel not using manuscripts for new molecular data based on gene expression changes because this data has not been vetted for estimation of potential risk.

24. Pp. 31-32. There are no microbiologists on the Panel. We recommend that the Panel have an established environmental microbiologist with expertise in water quality, public health, risk, and ABR review the recommended approach regarding antibiotic resistance prior to finalization of the report. One potential reviewer is Dr. Kellogg Schwab of Johns Hopkins University.

25. Pp. 31-32. No rationale is provided as to how the antibiotics addressed in the Report were chosen. Additional information should be provided in the Report on their selection.

26. Pg. 66, paragraph 1. "The majority of the studies were for freshwater species. Few studies of salt water species were identified. We added a 10-fold safety factor for sensitivities in salt water if only fresh water data was available." In studies where salt water and comparable freshwater species were identified, did the ratios of toxicity support a 10-fold safety factor?

Chapter 5

27. Pg. 33, paragraph 2, last sentence. This is an important distinction about analytical detection limits being developed based on practical analytical capability as opposed to ecosystem or health bioeffects relevance. Just because something is measured does not mean it is adversely affecting the environment.

28. Pp. 33-34. Organic chemicals were considered for screening even if no commercial laboratories were found to conduct analyses. One of the compounds for which we are not aware of commercial laboratory capability is fipronil, which is recommended for monitoring in effluent-dominated waterbodies. The Report should make it clear that monitoring need not be conducted if laboratory services for a particular compound or matrix cannot be obtained at a reasonable cost.

Chapter 6

29. Pg. 43, Table 6.1. We disagree with the PNECs listed for bifenthrin and permethrin, two pyrethroid pesticides. The PNECs were set equal to proposed aquatic life criteria that were derived from studies using Hyalella azteca (Fojut, et. al., 2012). Hyalella azteca is a sediment dwelling freshwater amphipod, but the testing used to derive the criteria was based on water-only exposures. The researchers that derived the criteria

acknowledge that sensitivity to pyrethroids in sediment dwelling organisms was up to 2.2 times higher when the same species was tested in a water-only matrix (M.E. DeLorenzo, L. Serrano, K.W. Chung, J. Hoguet, and P.B. Key. Effects of the insecticide permethrin on three life states of the grass shrimp, Palaemonetes pugio. Ecotoxicol Environ Safety 64:122-127). Because of this shortcoming, it is most appropriate to use a water column dwelling organisms such as Ceriodaphnia to derive the NOECs/PNECs. Furthermore, the researchers that developed the criteria clearly recognized that it is well documented that various water conditions and parameters such as temperature, dissolved organic carbon, TSS, and TDS can greatly reduce the toxicity of pyrethroids (September 2011 Water Quality Criteria Report for Permethrin. Phase III and September 2011 Water Quality Criteria Report for Bifenthrin. Phase III, both by T.L. Fojut, C. Rering, and R.S. Tejeerdema, prepared for the Central Valley Regional Water Quality Control Board). However, they were unable to incorporate or account for these conditions in derivation of the criteria due to data gaps. Therefore, the PNECs used in this evaluation failed to account for these mitigating factors. Finally, Hyalella azteca has been shown to develop resistance to pyrethroid pesticides in streams (e.g., Nautilus Environmental study in Upper Santa Magarita River). Multi-generational testing should be used to better predict long term impacts from pyrethroid pesticides.

30. Pg. 43, Table 6.1. A NOEC/PNEC of 56 ng/L is listed for chlorpyrifos, but per Table D.1 this should be 50 ng/L. The corresponding freshwater MTL and HQ should be adjusted accordingly.

31. Pg. 43, Table 6.1. We strongly caution the use of data from vitellogenin (VTG) induction studies of male fish as a basis for the estrone NOEC (6 ng/L). We recommend that any such data be carefully scrutinized since VTG induction in male fish can be highly variable and can be significantly impacted by the type of food that laboratory-cultured fish are fed. Fish food, particularly flake food, often contains soy with high levels of phytoestrogens that have been shown to induce VTG production in male fish. We recommend deriving the PNEC using an endpoint other than VTG induction in male fish.

32. Pg. 43, Table 6.1. A NOEC/PNEC of 11 ng/L is incorrectly listed for fipronil for the aqueous exposure in effluent-dominated waterways scenario. Appendix D (page 168) lists two NOECs for fipronil, a NOEC of 9800 ng/L for daphnia and a NOEC of < 5 ng/L for mysids. According to the reference from which these NOECs are derived (USEPA 1996), the appropriate NOEC for estuarine and marine animals is the < 5 ng/L value for mysids. This NOEC was correctly applied in Table 6.2 for coastal embayments. However, for freshwater a NOEC of 6600 ng/L applies for freshwater fish (larval growth in rainbow trout) and the NOEC of 9800 ng/L applies for freshwater invertebrates (length of daphnids). Using the lower of the two freshwater values would result in a NOEC of 6600 ng/L for fipronil. With a safety factor of 10 and an MEC of 11 ng/L, the HQ for fipronil in effluent dominated inland waterways is << 1, and thus monitoring for fipronil should not be recommended for such waterways. This is an important change, because we are not aware of any commercial laboratories that are analyzing for fipronil at this time.

33. Pg. 43, Table 6.1. A safety factor of 10 for "unknown mode of action" was applied to diclofenac. However, Appendix D (page 166) provides detailed information about impacts of diclofenac to kidneys, the endpoint upon which the NOEC was developed. This safety factor should be removed, and the resulting MTLs and HQs revised.

34. Pg. 43, Table 6.1. Column heading "NOEC or PNEC". Should this column be "NOEC" since "PNEC" was not used?

35. Pg. 44, Table 6.2. Column heading "NOEC PNEC". Should this column be "NOEC or PNEC" to clarify nomenclature?

36. Pp. 43-44, Tables 6.1 and 6.2. A safety factor of 10 for "EDC mode of action not incorporated into PNEC or NOEC" was applied to cis-androstenedione in freshwater, despite the NOEC being developed based on endocrine disruption impact (masculization of anal fin in females), per Appendix D, page 166. This safety factor should be removed, and the resulting MTLs and HQs revised.

37. Pp. 43-44, paragraph 1. Section 6.2.2 states that PECs were derived from MECs in Scenario 1, with a 10-fold dilution factor applied. However, Table 6.2 contains several MECs derived from stormwater concentrations (bisphenol A, bifenthrin, and chlorpyrifos). The text should be corrected to describe how these values were derived.

38. Pg. 44, Table 6.2. MECs for 17-beta estradiol and fipronil are listed in Table 6.2 as 3.0 and 25 ng/L, respectively, with a footnote indicating that these values were derived from freshwater (i.e., Scenario 1). The correct values from Scenario 1 are 8.4 and 11 ng/L, respectively.

39. Pg. 44, Table 6.2. A safety factor of 10 for "freshwater to saltwater" is applied to fipronil. However, the recommended NOEC is derived from an invertebrate life-cycle toxicity study using the estuarine organism mysid. Per the reference used for the NOEC (USEPA 1996), the NOEC applies to estuarine and marine animals. Therefore, a safety factor to translate from freshwater to saltwater is not appropriate.

40. Pg. 44, Table 6.3. The table lists the MECs in sediment for coastal embayments for bifenthrin and permethrin as 80 and 190 ng/g, respectively. However, Table 5.4 indicates that these values are for ocean sediment, not embayment or estuary sediment. The ocean values should not be applied to the embayment scenario. Literature should be reviewed to obtain embayment sediment values for these chemicals.

41. Pg. 44, Table 6.3. The table includes an overall safety factor of 1000 for bifenthrin and permethrin in coastal embayment sediment. The overall safety factor includes a factor of 10 to translate from an acute to a chronic NOEC. However, the NOEC for these two chemicals is based on a chronic endpoint, growth. Therefore, the safety factor to translate from an acute to a chronic NOEC should be removed.

42. Pg. 45, Table 6.4. The NOEC listed in Table 6.4 for p-nonylphenol is 14,000 ng/g. However, page 171 of Appendix D indicates that the correct NOEC is 1,400 ng/g (i.e., 1,400 ug/kg).

43. Pg. 45, Table 6.4. A safety factor of 100 for "freshwater to saltwater" and "EDC mode of action" was applied to p-nonylphenol in ocean sediment, despite consideration of endocrine disruption effects in one study (Hansen, et. al., 1999 considered growth and fecundity), the inclusion of a 50x safety factor in the interim sediment quality guideline (ISQG) that was used as the NOEC, and use of seawater in the experiments used to develop the NOEC (as detailed in Appendix D). The safety factor for p-nonylphenol in ocean sediment should be 1.

44. Pg. 45, Table 6.4. The MEC for PBDE-47 and PBDE-99 is listed as 4.4 ng/g. Table 5.4, however, lists the ocean sediment MEC for PBDE-47 and PBDE-99 as 122 ng/g.

45. Pg. 45, Table 6.4. The NOEC for PBDE-47 and PBDE-99 is listed as 3 ng/g. It is impossible to determine how this value was derived This NOEC for sediment is not listed in Tables D.1 or D.2, and no write up is provided in the appropriate section of Appendix D (page 171).

46. Pg. 46, Table 6.5. The table includes a safety factor of 10 for PBDE-47 and PBDE-99 in tissue. No explanation is provided as to why the safety factor is included. The study on which the NOEC is based considered endocrine disruption impacts (fertility, hatching, fledging, egg thinning, etc.).

47. Pg. 47, paragraph 1. We support the Panel using comparison of antibacterial/antibiotic environmental concentrations to minimum inhibitory thresholds (MICs) to develop an initial list of antimicrobials/antibiotics for monitoring. While we believe there may be limitations to the relevance of this approach, given the current state of knowledge it appears to be the best method available at this time.

48. Pg. 47, paragraph 1. Use of the term "NOEC" in relation to MICs is very confusing. The term NOEC is normally used to describe concentrations at which adverse impacts on organisms occur. However, for the antibacterials/antibiotics the purpose of the assessment is not to set a threshold at which organisms are harmed, but rather to set a threshold under which ABR bacteria are not likely to be formed.

Chapter 7

49. Pg. 49, paragraph 2. Explaining genotoxicity and steriodgenis endpoints would be helpful for non toxicologists reviewing this report.

50. Pg. 50, last sentence. Tri-TAC appreciates that the Panel recognizes round robin experiments at multiple locations needs to occur for bioanalytical assays to be used for monitoring and regulatory purposes.

51. Pg. 55, paragraph 2. The Report suggests that the presence of low concentrations of antibiotics in the environment can promote ABR in bacteria. This is overstating the issue, since at this time we do not know if this actually occurs. The purpose of the monitoring recommended by the Panel is to be able to understand this issue better. Language in this paragraph should be softened, particularly with regard to ABR bacteria eventually taking over the population.

52. Pp. 49-55. The Panel discusses and proposes the use of high throughput in vitro bioassays that are still under development. These bioassays are a number of years away from being ready for commercial availability. When they become available, they will require extensive validation and round robin testing before they are ready for use, and we appreciate the recognition by the Panel that this testing should be performed.

53. Pp. 49-55. The methods discussed in Chapter 7 are of a highly technical nature and most require a very high level of expertise and laboratory infrastructure. This fact will have to be taken into consideration as Phase 2 monitoring workplans and studies are developed. Many of the methods discussed are not common to contract laboratories, utilities, or academic laboratories and the cost of startup and development makes many of them prohibitive.

54. Pg. 49, paragraph 2. The report notes that main advantage of bioassays is their ability to detect the presence of chemicals based on bioactivity and further notes that, for bioassays to be useful, robust, reproducible, high throughput in vitro assays need to be developed. The Report should also state at this point that the in vitro assays developed need to have been calibrated against in vivo assays that examine an endpoint or endpoints that are relevant at the population level. (e.g., "For this to work, however, robust, reproducible and high throughput (HTP) in vitro assays need to be developed that have been closely calibrated against in vivo assays that examine an endpoint or endpoints that are relevant at the population level.")

55. Pg. 56, Box 7.1. The box includes a discussion of how copepods can adapt quickly to certain CECs, so that multi-generational testing should be used to better predict long-term chronic impacts. The same effect has been observed for Hyalella responding to pyrethroid pesticides (e.g., Nautilus Environmental study in Upper Santa Margarita River). Since pyrethroid pesticides were identified for monitoring in the Report, a discussion of Hyalella development of resistance to pyrethroid pesticides should be added to Box 7.1.

Chapter 8

56. Pg. 60, Figure 8.1. The Phase 1 box for determining a preliminary list of CECs for monitoring includes considering cost for available analytical methods before classifying/prioritizing CECs by their physical-chemical, and toxicity data. This consideration of cost for classifying/prioritizing should be expressed better in the text describing Phase 1.

57. Pg. 61, Question 2. The question addresses marine waters and sediments adjacent to WWTP outfalls. However, to better capture environmental impacts, this question should be broadened to include large (> 36") storm drains that discharge to intertidal or shallow subtidal areas.

58. Pp 62-63. Tri-TAC strongly supports the implementation of the Report's recommended monitoring programs through state-wide, regional, and local monitoring programs, rather than through individual monitoring requirements in NPDES permits. Requiring individual monitoring in all NPDES permits would consume resources that are better dedicated toward studies in the pilot areas proposed by the panel. The Panel should clearly state that it is not their intent for WWTPs to be individually required to monitor for the list of "WWTP Effluent" compounds indicated in Table 8.1.

59. Pg. 63, Table 8.1. While the previous chapters of the report focused on the three scenarios for CEC risk assessment, Table 8.1 introduces a column for monitoring of "FW Stream. Stormwater (Aqueous and sediment). The table contains a footnote to explain this addition of stormwater monitoring (i.e., to address the data gap on relative contributions of stormwater discharge and WWTP effluent). However, the authors should include a discussion in the text of the report to better explain the necessity of stormwater monitoring, and to discuss the scope of stormwater monitoring needed to close the data gap.

60. Pg. 63, Table 8.1. The table lists CECs for stormwater aqueous monitoring and stormwater sediment monitoring in the same column. It is recommended that separate lists of CECs be provided for aqueous and sediment monitoring for stormwater. While the list of chemicals in the stormwater column appears to be appropriate for an aqueous matrix, it seems overly broad for sediment monitoring. The list includes a number of compounds that are not specified for embayment sediment or marine sediment, and the authors have not provided justification as to why such a broad list is needed for stormwater sediment. The authors should consider using the embayment sediment list of chemicals for sediment in stormwater-dominated streams.

61. Pg. 64, paragraph 1. The Panel proposes that validation studies be performed for each of the analytical methods used. We strongly support this and feel that method selection and validation is a critical aspect to the overall success of the monitoring program. Ideally, each of the selected biological assays and analytical chemistry methods should be validated and tested through a round robin process. We also support development of standards for analytical sensitivity, reproducibility, and robustness.

62. Pg. 64, paragraph 1. Could you explain, or give an example of a regional permit, and explain where they are necessary?

63. Pg. 64, Table 8.2. The table contains a detailed description of recommended Phase 2 monitoring. It appears that the monitoring recommended in Table 8.2 is intended to represent the full extent of a state-wide program for CEC monitoring, but this is not

fully clear. Footnotes a-d to Table 8.2 discuss potential locations for "pilot investigations", but do not discuss potential locations for the full chemical monitoring. Is chemical monitoring to be conducted only in the locations suggested in footnotes a–d? For example, for POTWs discharging to effluent dominated waterways, Table 8.2 recommends monitoring for one POTW and one receiving water. Is this the extent of the statewide monitoring program, or is every POTW in the state discharging to an effluent dominated waterway supposed to monitor at the POTW and in the receiving water?

64. Pg. 64, Table 8.2. The table specifies that "aqueous sampling" is to be conducted for large POTWs discharging to the ocean. However, Chapter 6 of the report indicates that receiving water aqueous sampling is not appropriate under this scenario. If it is the intent of the authors that aqueous sampling of only POTW effluent, not receiving water, should be conducted for this scenario, then clarification should be added to the report.

65. Pg. 64, Table 8.2. "Two POTWs and corresponding RWs", "Five POTWs in one estuary/embayment", "Two large FW streams and the Delta", "One POTW and RW". Please identify the stakeholders and resource requirements including analytical and technical support.

66. Pg. 64, Table 8.2. the table specifies that sediment monitoring is to be conducted for effluent dominated waterways, but Table 8.1 does not provide a list of the required constituents. Please clarify.

67. Pp. 64 to 65. On page 59, the Report clearly states that methods may not be available for all CECs in all matrices, and that if a method is not available then one would need to be developed or a PEC estimated before the CEC can be considered for Phase 2 monitoring. This is an important caveat that may be missed by stakeholders that focus solely on the Monitoring Program Design Guidance provided on pages 64 and 65. The Report should include this important caveat regarding monitoring on page 64 or 65.

68. Pg. 65, Table 8.2. In Table 8.2 the Panel provides guidance for the development of monitoring workplans and studies. The Panel specifically recommends the use of bioanalytical screening assays and one toxicity assay (the 21-day fathead minnow recrudescence assay). We recommend that concurrent whole effluent toxicity (WET) assays be included in this process in order to help answer Question 9 on page 62. Such WET data might be easily accessed from NPDES monitoring programs and integrated into the monitoring program design, thereby helping to defray costs.

69. Pg. 65. While the Panel includes bioanalytical screening assays as part of the monitoring workplans and studies they provide no guidance on how data from these assays should be used in the overall monitoring scheme (Figure 8.1). Such guidance should be included in the Report. Many of these bioassays only provide information on exposure but say nothing about higher order effects. We recommend that the Panel

add establishment of links between bioassays and higher order effects as part of the validation and monitoring studies.

70. Pg. 66, paragraph 1. "In essence, the intent is to evaluate the Phase 2 results within the context of a tiered risk-based monitoring and response framework as presented in Figure 8.2. This approach balances the potential risks, including uncertainty, against escalating actions." There are four tiers described in Figure 8.2. What is the criterion to be used for each tier? What is the technical basis for the criteria? The left side y-axis is labeled "Concentration/Risk". Is this the HQ=MEC/MTL? Please define "Concentration/Risk". The right side y-axis is labeled "Regulation". What is meant by regulation?

71. Pg. 66, paragraph 1. "It should be noted that the Phase 1 and 2 monitoring recommendations by the Panel should not be considered for compliance and/or regulatory purposes, but for investigation and potential use for additional follow-up actions." This sentence appears to be in conflict with Figure 8.2 which appears to establish tiers for "Concentration/Risk" and "Regulation".

Chapter 9

72. Pg. 68, last paragraph. The Panel indicates that bioanalytical techniques that can be linked to higher order impacts are greatly needed and should be utilized as part of this effort. We strongly agree and feel that this cannot be overstated, considering that the *in vitro* bioassays have in most cases not been linked to higher order effects such as survival, growth, reproduction, or resistance to disease. Such a linkage is essential to establish the utility of a screening bioassay. Furthermore, the Panel also proposes the use of microarray technology. Much work is still needed in order to connect transcriptional changes (as detected by microarrays) with higher order effects. We feel that the Panel should more strongly emphasize the appropriateness of methods that demonstrate higher order effects versus those that only demonstrate exposure. The majority of the methods that the Panel discusses are, to date, only capable of demonstrating exposure. Furthermore, due to the central importance of establishing linkages between bioassays and higher order effects, pilot studies addressing such linkages should be added to the recommended monitoring program. Otherwise, it is likely that funding will not be available to tackle this important research priority.

73. Pg. 69. The first issue listed (i.e., "Analytical method development cannot keep up with need to monitor newly identified CECs.") should be expanded to note that analytical method development also cannot keep up with the need to monitor CEC degradation products.

74. Pg. 69. The second research need listed mentions the need to link adverse outcome pathways to higher order endpoints by performing the 21-day reproductive assay in combination with gene microarrays. However, the 21-day reproductive assay is currently only available for a freshwater species (i.e., fathead minnows). The Report should recognize the need to develop a marine version of the fathead minnow 21-day assay, and should recommend that it be developed.

75. Pg. 70. The Panel envisions a transition from chemical-specific to bioanalytical monitoring. However, the Panel needs to recognize that chemical monitoring will always be necessary for use in conjunction with bioanalytical monitoring. Once a biological effect has been identified, it is necessary to use chemical monitoring techniques to establish which chemical (or chemicals) is causing the effect. Once the chemical cause of the biological effect has been identified, then steps can be taken to locate the source of the chemical and reduce its discharge. Furthermore, we would strongly object to any future regulatory action to be based exclusively on biological methods; future regulatory action should instead be based on the control of the chemical (or chemicals) identified to be causing the biological impact.

Appendix C

76. Pg. 82, paragraph 1. "Concerns that drinking water augmentation may contain antibiotics and antimicrobials in trace amounts are not likely to be a problem in California water recycling programs, but they are addressed specifically below." It would be helpful to elaborate on why this isn't a California issue based on the subsequent information provided in the appendix, which could be interpreted to mean it is a problem.

Appendix D

77. Appendix D includes the information used for NOEC determination for CECs that exceeded HQs of 1. We very much appreciate inclusion of this information, as it made the Report much more transparent and easier to review.

78. Pg. 188, paragraph 1. No rationale is provided for why an initial safety factor of 100 was used, instead of an initial safety factor of 10. Safety factors generally start at 10 and are applied incrementally upward from there.

79. Pp. 189-192. The Report provides a good explanation regarding the need to better understand the significance of antibiotic resistance in the environment.

Appendix F

80. Pg. 218, paragraph 3. The Panel recommends that levels of ABR in E. coli or other indicator bacteria be investigated by establishing baseline conditions for effluents and sediments at several WWTP outfalls as a starting point. While we believe that investigation of WWTP effluent is a reasonable starting point that will generate much needed data on ABR, we believe that sampling for sediment associated with outfalls is not warranted at this time. Rather, any sediment sampling should be postponed until effluent characterization has been completed, so that results from effluent analysis can inform any sediment monitoring.

81. Pg. 218, paragraph 4. The Panel proposes an ABR screening bioassay developed by NOAA and Siemens (Dade Behring's MicroScan system) but states that equivalent approaches may be used. The MicroScan bioassay is used in clinical microbiology settings for determination of ABR. It is customizable, but the format as discussed by the Panel analyzes for resistance to 26 antimicrobials at three different concentrations (10% MIC, 100% MIC, and 200% MIC). There are other similar systems on the

market by Becton-Dickinson (Phoenix) and bioMerieux (VITEK). On the surface, the bioassay sounds legitimate for this application; however, it is impossible to fully evaluate the assay without looking at the manufacturer's protocol. The Panel also references data that is in press so it is not possible to fully evaluate its utility at this point.

82. Pg. 218. Whatever ABR assay is selected for use as part of the monitoring effort needs to be rigorously validated and testing in a round robin process.

83. Pp. 218-220. While we believe that investigation of ABR bacteria in WWTP effluents is a good first step forward to understand the contribution, if any, of WWTPs to transmission of ABR, we caution the Panel that resistance of the bacteria in a WWTP effluent to a particular antibiotic is not necessarily expected to be correlated with the presence or concentration of that antibiotic in the effluent. Instead, the types of ABR bacteria entering the plant is expected to be driven by loadings of the ABR bacteria into sewers from human sources, and the types of ABR bacteria exiting the plant are expected to be driven by the ability of the bacteria to survive the treatment process.

84. Pp. 218-220. We caution the Panel that the results from Uyagauri et. al. (2011) showing enrichment of the final effluent in ABR gene material may not be typical of all wastewater treatment plants.

85. Pp. 218-220. Given the extremely limited state of knowledge regarding ABR bacteria in WWTP effluent, it is premature at this time to develop a prescriptive protocol for classification of results and for requiring further action based on an experimental ABR screening bioassay. While it appears to be a good idea to monitor for all antibiotics for which at least moderate resistance is indicated in WWTP effluent, monitoring methods may not be commercially available and monitoring for some antibiotics may be extremely difficult. Furthermore, not all bacteria in the WWTP effluent will have the same ABR characteristics; instead a population with a range of ABR characteristics will be present. Knowledge on the ABR characteristics of the effluent bacteria population, along with consideration of method availability, should drive the choice for further antibiotic monitoring.

86. Pg. 220. We strongly object to scheme proposed to classify the number of antibiotics to which resistance is measured as "Low Hazard," "Moderate Hazard," or "High Hazard." The term "hazard" indicates a serious threat. At this time, we do not yet understand the significance of ABR bacteria in the environment. Although there is a great deal of ongoing clinical research in this area, very little information is available regarding the significance of ABR in the environment and the role that its existence had on the environment, ecological receptors, and human health. In short, there is no known "hazard" associated with the presence of bacteria with multiple antibiotic resistance (MAR) in low concentrations in the environment, and use of the term "hazard" could cause unnecessary public alarm over WWTP discharges.

87. Pg. 220. While we support collecting data to begin to understand any relationship between WWTP effluents and ABR, we caution that information collection alone will

not be enough to understand what the data mean and whether and/or how WWTP effluents contribute to ABR. We therefore encourage efforts to develop a well-reasoned framework for interpreting antibiotic and ABR bacteria results.

88. Pg. 218-200. We support the Panel's decision to leave open for additional research the possibility of ABR driven by gene elements (e.g., free DNA, plasmids, integrons).

Non-substantive Comments

89. Pp. iv and v. The Report states that eleven compounds were identified for freshwater systems, but it lists twelve compounds.

90. Pg. 7, paragraph 2. The Report states, "The potential for antibiotic resistance (ABR) was evaluated for indicator bacteria or pathogens…" The approach described in the Report only relies on indicator bacteria, not pathogens. The phrase "or pathogens" should be deleted.

91. Pg. 18. The second sentence of the first paragraph in Section 3.1.1 (i.e., Although most CECs occur in trace concentrations…) is somewhat misleading and stems from the SCCWRP flatfish study. The reason the mass loading of CECs is comparable to trace metals is also due to the higher number of CECs measured (approximately 80) in that study relative to the number of trace metals monitored as priority pollutants.

92. Pg. 23. The Report states that certain areas of the SCB and other parts of the cost of California "have historical sediments that contain compounds that are herein considered CECs and that may contribute CECs the environment." It is not clear if this statement is referring to DDTs, PCBs, or some other compound or compounds. An example should be added in parentheses for clarity, such as "(e.g., PCBs)".

93. Pp. 23-24. The Report states that a recent study in the SCB "suggested outfall dilution factors of ~1000 in near-bottom water." To be accurate, this should be changed to "suggested outfall dilution factors of ~1000 or more in near-bottom water."

94. Pg. 31. "Fish Consumption Goal" should be changed to "Fish Contaminant Goal."

95. Pg. 33. Kumar and Xagoraraki 2010 is listed as a reference, but the full citation for this paper is not included in the References section.

96. Pg. 37, Table 5.2. The table lists the tiers associated with the data used to develop maximum aqueous concentrations of CECs. Tier 1 is data from the CEC Recycled Water Panel and Tier 2 is other data from within California. However, two compounds are listed as having Tier 1 data when Appendix E cites a reference other than the CEC Recycled Water Panel Report (chlorpyrifos and cis-androstenedione).

97. Pg. 40. A footnote should be added to Table 5.4 explaining the acronym "NM".

98. Pg. 43, Table 6.1. The table lists a water column NOEC/PNEC for bifenthrin, but the NOEC/PNEC for this compound is not included in Tables D.1 or D.2.

99. Pg. 44, Table 6.3. The table lists NOECs for bifenthrin, permethrin, PDBE-47, and PBDE-99, but these NOECs are not included in Tables D.1 or D.2.

100. Pg. 44, Table 6.3. Estuarine Sediment MTL (ng/g) for bifenthrin is reported as 0.052. NOEC / Safety Factor = 5.2 / 1000 = 0.0052. Please recheck this value. If true, the HQ then becomes 15,000. Also please refer to comment 29.

101. Pg. 43. Units of ng/L should be indicated for the "Freshwater MTL" column in Table 8.1.

102. Pg. 47. The explanation of why a safety factor of 100 was applied to the most sensitive MIC for antibiotics should be moved from the appendices to the text of Section 6.4. Without reading the appendices, the choice of a safety factor of 100 appears to be arbitrary.

103. Pg. 51. The phrase "thus providing a false sense of security or false indication of potential risk" is awkward. Better wording would be "thus providing an inaccurate assessment of potential risk."

104. Pg. 55, paragraph 3. Please provide a reference for the statement, "NOAA has developed an effective assay to screen for antibiotic resistance."

105. Pg. 63. Table 8.1. The table includes HQs for some parameters and scenarios in parentheses. The HQs are not necessary in this table and thus should be deleted.

106. Pg. 63, Table 8.1. The table lists "M-M" as the recommended initial monitoring for p-nonylphenol. This should be changed to "M-O", to indicate that monitoring need only be done at facilities with discharges to ocean waters.

107. Pg. 64, Table 8.2. The table contains a duplicate of the row "Spatial coverage. Receiving Water (RW)".

108. Pg. 69. Change "Toxicity of mixtures remains difficult to assess" to "Toxicity of mixtures and CEC degradation products remains difficult to assess."

109. Pg. 169. Lam et. al. 2010 is listed as a reference, but the full citation for this paper is not included in the References section.

110. Pg. 171. The sediment exposure section of Scenario 3 should mention that a writeup on PBDE toxicity in sediments is included under Scenario 2 (page 169).

111. Pg. 172. The PNEC for PFOS is listed on page 172 as 600 ug/kg. However, both Table 6.5 and Table D.1 list the PNEC for PFOS as 1000 ug/kg.

112. Pg. 176. The PNEC for bisphenol A is listed as 6 x 10-6 mg/L. Per page 168, this should be 6 x 10-5.

113. Pg. 176. No reference is listed for Bisphenol A.

114. Pg. 177. Table D.1 is missing information for bis(2-ethylhexyl)phthalate.

115. Pg. 177. No reference is listed for fipronil.

116. Pg. 178. Table D.1 is missing information regarding the sediment NOEC for p-nonylphenol.

Pp. 191-192. The reference "Uyaguari et al., 2011 in press" is used several times. We were unable to locate a