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June 26, 2018

Via Email

Jeanine Townsend
Clerk to the Board
State Water Resources Control Board
1001 I Street, 24th Floor
Sacramento, CA 95814



Subject: **Comment Letter – Proposed Recycled Water Policy Amendment**

Dear Ms. Townsend:

Orange County Water District (OCWD) staff is pleased to comment on the State Water Resources Control Board's (State Board's) proposed Recycled Water Policy Amendment.

OCWD is the public agency responsible for groundwater resource management in the Orange County Groundwater Basin. We represent the interests of more than 20 cities and retail water agencies that serve groundwater to nearly 2.5 million people in northern Orange County. In partnership with the Orange County Sanitation District, OCWD operates the Groundwater Replenishment System (GWRS), the country's largest indirect potable reuse project that provides 100 million gallons per day (MGD) of purified recycled water for groundwater recharge under permit from the Santa Ana Regional Water Quality Control Board (RWQCB) and the Division of Drinking Water (DDW). We also operate the Green Acres Project (GAP), a non-potable reuse project that supplies recycled water for landscape irrigation.

OCWD staff has historically supported the State Board's science-based process to inform constituents of emerging concern (CEC) monitoring requirements for recycled water, going back to the original 2009 Recycled Water Policy and the resulting first Science Advisory Panel (Panel) convened thereafter. We also generally support the State Board's efforts to update and clarify the provisions of the existing Recycled Water Policy, inasmuch the changes enhance the development of recycled water supplies to meet the amended Policy's ambitious goals. However, we are concerned with many of the changes and additions to the Policy's CEC monitoring requirements for potable reuse projects found in Attachment A, especially those related to the implementation of bioanalytical monitoring. Our concerns stem primarily from the significant deviations from the Final Report issued by State Board's Science Advisory Panel, entitled "Monitoring Strategies for Constituents of Emerging Concern (CECs) in Recycled

Water” (Final CEC Panel Report)¹. One source of these deviations was revealed at the June 19th Public Hearing, when State Board staff stated that important provisions within the proposed Recycled Water Policy Amendment were based on the earlier Draft CEC Panel Report issued on January 31st and that these had not been updated to reflect the recommendations within the Panel’s Final Report. This approach is concerning, as it undermines the long-held consensus between the State Board and its stakeholders for convening the Panel, as codified in the 2009 Recycled Water Policy; namely, to “guide future actions relating to [CECs]”. We are willing to accept the concept of bioanalytical monitoring at our potable reuse facility, but to instigate such monitoring without following the Final CEC Panel Report’s implementation guidance is unwise and unjustified, and will cause significant resources to be expended to generate data of uncertain quality that can trigger regulatory actions.

Our specific concerns and suggested modifications are described below.

1. Inclusion of Response Actions and Monitoring Trigger Levels for Bioanalytical Screening Tools

Section 5.3 (Evaluation of Bioanalytical Screening Tool Results) of Attachment A contains requirements for the project proponent or recycled water producer to perform specified Response Actions based on the results required bioanalytical screening tool monitoring results. Table 9 presents the Required Equivalency of Agonists and Monitoring Trigger Levels for Bioanalytical Screening Tools and Table 10 lists Bioanalytical Equivalent Concentration (BEQ) to Monitoring Trigger Level (MTL) ratios with accompanying required Response Actions.

As presented below, the inclusion of Response Actions and Monitoring Trigger Levels for Bioanalytical Screening Tools conflicts directly with the clear and unambiguous recommendations found in no less than eight parts of the Final CEC Panel Report, as well as additional recommendations found within subsequent correspondence between State Board staff and the Panel:

- pg. xi, Executive Summary of Final CEC Panel Report: “*While the Panel has outlined a process to interpret and respond to in vitro bioassay results, **this process is not sufficiently mature to justify response actions at this time.** Thus, the Panel recommends a phased implementation of bioanalytical screening, with Phase I consisting of a three to five-year data collection period, **with no response actions required during this time.**”*
- pg. x, Executive Summary of Final CEC Panel Report: “*As interpretive guidance for bioscreening data is not yet mature, **response actions such as identification of bioactive chemicals...should not be required during the data collection phase.**”*
- pg. 75-76, Section 7.3 – Interpreting Bioanalytical Results, Final CEC Panel Report: “*The Panel recognizes that **establishing screening-level***

¹ Drewes JE, Anderson P, Denslow N, Jakubowski W, Olivieri A, Schlenk D, Snyder S. 2018. Monitoring Strategies for Constituents of Emerging Concern (CECs) in Recycled Water – Recommendations of a Science Advisory Panel. Final Report. Convened by the State Water Resources Control Board.

- **thresholds and a robust interpretive framework are in their infancy** and are subject to improvement and refinement as more IVB monitoring data are collected and evaluated. Thus, the Panel believes it is **premature to require any such actions in response to bioassay results** during the first phase of IVB data collection...”
- pg. 78, Section 7.3.3 – Interpreting Appropriate Response Actions to Bioscreening Results, Final CEC Panel Report: “Absent the benefit of established IVB MTLs and recycled water IVB data, **the Panel felt it was premature to propose a framework describing appropriate responses to varying BEQ/MTL ratios at this time.**”
- pg. 81, Section 7.4.1 – Phase I Recommendations for Monitoring of Potable Reuse Projects, Final CEC Panel Report: “Whereas interpretive guidance for bioanalytical screening results are provided in section 7.3, **the Panel believes that requiring response actions to screening results for the Phase I data collection exercise is premature.**”
- pg. 82, Section 7.4.3 – Bioscreening Implementation Advisory Group, Final CEC Panel Report: “...**requiring response actions during the initial data collection phase is premature and thus not appropriate**, until such methods are fully validated and certified by the appropriate entities [e.g. the State Water Board’s Environmental Lab Accreditation Program (ELAP)], and that **the interpretive framework outlined in 7.3 has matured and has been subject to a critical evaluation by water quality experts, State Water Board personnel and stakeholder representatives.**”
- pg. 83, Section 7.6 – Conclusions, Final CEC Panel Report: “**However, the Panel feels that requiring response actions during Phase I data collection is premature.**”
- pg. 102, Section 9.4 – Updated 2018 CEC Monitoring Recommendations for Potable Reuse Practices: “...**the Panel feels that requiring response actions to bioassay results is premature at this time.**”
- pg. 1, Memorandum on Bioanalytical Monitoring Trigger Levels²: “At this time, the Panel also stresses that their recommendations for bioscreening **should not be misconstrued as suitable for incorporation into the [Recycled Water Policy] as a regulatory limit for compliance** but rather, as noted above, for screening level analysis only. For example, **the term “action level” in the current draft report could lead to misinterpretation of the Panel’s intent**, even though the steps for interpreting bioscreening results are clearly delineated in the draft report (see Section 7.5.3) **as adaptive, flexible, non-binding and non-regulatory.**”

² Memorandum on Bioanalytical Monitoring Trigger Levels, from Keith Maruya (SCCWRP/CEC Panel Facilitator) to Tessa Fojut (State Board staff), dated May 14, 2018, available at: https://www.waterboards.ca.gov/water_issues/programs/water_recycling_policy/docs/panel_memo_bioscreening_rev_180514.pdf

Within both the proposed Recycled Water Policy Amendment and its accompanying draft staff report, as well as during the Bioanalytical Screening of Recycled Water Workshop held at SCCWRP on June 11th, State Board staff have cited the current requirement for Response Actions and Monitoring Trigger Levels to evaluate CEC monitoring results from targeted analytical chemistry methods as the basis for adopting equivalent Response Actions for bioanalytical monitoring results. However, this assigns a false equivalence between targeted analytical chemistry methods and bioanalytical screening tools as applied to recycled water monitoring; the analytical chemistry methods were significantly more established, standardized, and mature when targeted CEC monitoring was made a requirement within the 2013 Recycled Water Policy, and are even more standardized today, as compared to the relative immaturity of bioanalytical screening tools applied to regular recycled water compliance monitoring.

The draft State Board staff report also claims that *“Providing monitoring trigger levels to compare bioanalytical screening tool results to and response actions for different levels of bioanalytical results provides context for the results and why there is a need for monitoring with bioanalytical screening tools. If monitoring trigger levels, which are thresholds of concern based on human health effects, were not included, then the need to monitor with bioanalytical screening tools would not be clear.”* (pg. 73, Section 4.14.2). In actuality, the State Board has numerous other options to require the collection of bioanalytical data from recycled water projects without requiring Response Actions and Monitoring Trigger Levels. One such approach that deserves consideration is the implementation of an Unregulated Contaminant Monitoring Rule (UCMR) style program, such as those previously administered by both the State of California and USEPA to assess drinking water. Such an UCMR program could require specified bioanalytical monitoring in recycled water for a limited period of time. Like the drinking water UCMR, it could require laboratories to first demonstrate proficiency with bioanalytical techniques according to established protocols ahead of performing the required monitoring and analysis, with results reported to the State.

As such, we concur with the Final CEC Panel recommendations that the inclusion of Response Actions and Monitoring Trigger Levels for bioanalytical screening tools is premature and not appropriate, and therefore request that they be removed from the proposed Recycled Water Policy Amendment. At the very least, any Response Actions included in the Policy should be limited to supplementary data collection actions only (e.g., repeat sampling or split-sampling if certain thresholds are exceeded), as this would be consistent with the Final CEC Report recommendation for the initial phase of required bioanalytical monitoring be focused exclusively on data collection. Furthermore, previous State and USEPA UCMR drinking water monitoring programs provide a model for implementing bioanalytical monitoring without Response Actions and Monitoring Trigger Levels.

2. Ignoring the Panel’s Recommended Phased Approach for Bioanalytical Tool Monitoring Implementation

The Final CEC Panel Report recommends a very methodical, deliberate, and carefully considered approach to the implementation of bioanalytical monitoring for

recycled water. This approach is clearly described in Section 7.4 (Phased Implementation of Bioscreening of Recycled Water) and features three phases:

- **Phase I:** a data collection exercise to determine the range of responses for IVBs standardized for water quality monitoring (i.e. Stage 3 of *(sic)* higher in Table 7.2) and that represent endpoints relevant to human health in designated samples from recycled water facilities across the state. A review of the bioscreening data collected during Phase I by the Panel is recommended at the end of the Phase I data collection period.
- **Phase II:** a pilot evaluation of the interpretive framework for bioanalytical monitoring results (described in section 7.3), with initial MTLs established to further guide appropriate response actions geared toward ensuring a high quality of recycled water.
- **Phase III:** full implementation of bioanalytical monitoring, where validated and certified bioanalytical methods would be an integral component of routine screening/monitoring of recycled water quality.

The “phased monitoring” approach within the proposed Recycled Water Policy Amendment is an entirely different construct as compared to these Panel recommendations. It simply takes the monitoring frequencies currently required for targeted analytical chemistry monitoring for CECs and applies them to bioanalytical tool monitoring:

- Initial Assessment: One year of quarterly monitoring
- Baseline: Three Years of semi-annual monitoring
- Standard Operating: Ongoing semi-annual monitoring

Figure 1 below, also presented by stakeholders³ at the June 11th Bioanalytical Screening of Recycled Water Workshop held at SCCWRP, presents the differing “phased” approaches proposed by the Final CEC Panel Report and the Recycled Water Policy Amendment.

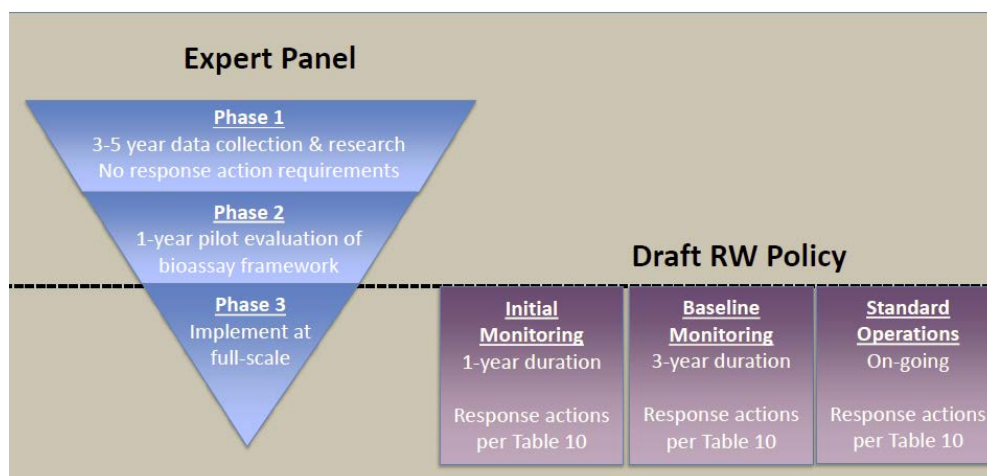


Figure 1: Comparison of Panel & Draft Recycled Water Policy Implementation

³ https://www.waterboards.ca.gov/water_issues/programs/water_recycling_policy/docs/2018/west_plumlee.pdf

The “phased monitoring” within the currently proposed Recycled Water Policy Amendment again implies a false equivalence between the current status of targeted analytical chemistry monitoring for CECs and bioanalytical tools. It ignores the current lack of standard protocols and procedures for the sampling, preservation, extraction, measurement, QA/QC, data reporting, and the interpretation of bioassay results, all of which the Panel’s phased implementation plan is intended to address. The draft Policy’s currently proposed “phased monitoring” approach is likely to lead to the generation of data that cannot be reliably compared across sites or laboratories, and therefore cannot be rigorously assessed to inform future monitoring, due to the wide variety of unstandardized protocols currently in use. **We strongly believe the Panel’s thoughtfully developed implementation approach is superior and should be reflected in the proposed Recycled Water Policy Amendment.**

3. Ignoring the Panel’s Recommendation to convene a Bioscreening Implementation Advisory Group

As a part of its phased implementation of Bioanalytical Tool Monitoring, the Panel recommends that the State Board convene a Bioscreening Implementation Advisory Group (Section 7.4.3 of Final CEC Panel Report) to guide its recommended Phase I. According to the Panel, this group:

..”could consist of select Panel and SAG members, bioanalytical application experts, State Water Board staff and representatives from the commercial services industry who would ultimately be tasked to perform such measurements. The group would define goals for bioanalytical monitoring, specify protocols for sampling, extraction, measurement and data reporting, and provide guidance for interpretation of bioanalytical monitoring results, including QA/QC data. To maximize commonality and consistency of the guidance provided, the group would also interact with on-going and future efforts to develop, evaluate and apply bioanalytical tools for water quality screening, particularly those supported by the State Water Board and/or recycled water research organizations working with the State Water Board.”

The proposed Recycled Water Policy Amendment does not include a Bioscreening Implementation Advisory Group, nor does it acknowledge the underlying need for such a group; namely, the immaturity and associated lack of widely-accepted standard protocols for carrying out bioanalytical monitoring outside of a research environment. Relatedly, we believe that the perspective of commercial laboratory service providers in California has yet to meaningfully inform the currently proposed implementation process. **Per the Panel’s recommendation, the convening of such a group to assist with the initial implementation of the bioanalytical tool monitoring in recycled water should be included in the Recycled Water Policy Amendment.** Should State Board resources not be available to support the implementation of this group during the initial bioanalytical monitoring, numerous stakeholders within the water recycling community would likely be willing to support it to ensure the successful implementation of bioanalytical monitoring.

4. Implied Widespread Standardization of Bioanalytical Monitoring Protocols

Implied throughout Attachment A is the idea that the two proposed bioanalytical monitoring tools, the Estrogen receptor- α (ER- α) and the Aryl hydrocarbon receptor (AhR), are sufficiently developed and standardized such that they can be carried out on behalf of recycled water project proponents by multiple commercial laboratories using similar techniques, thereby generating reproducible and comparable data across recycled water facilities and laboratories in a manner analogous to targeted analytical chemistry methods. However, as stated previously, this draws a false equivalence and overstates the readiness of bioanalytical tools for regulatory-driven monitoring.

As a part of a research effort and prior to the release of the proposed Recycled Water Policy Amendment, OCWD staff contacted the four commercial laboratories listed in the Final CEC Panel report (pg. 71, Section 7.2) that are purported to offer bioanalytical monitoring services for the ER- α and AhR assays: BDS, INDIGO Biosciences, IonTox, and Attagene, Inc. OCWD was seeking quotes to incorporate the ER- α and AhR assays into a recycled water research project. A summary of OCWD's first-hand experiences is presented below:

- None of the four laboratories are located in California, but instead in Michigan (IonTox), Pennsylvania (INDIGO Biosciences), North Carolina (Attagene), and Amsterdam in The Netherlands (BDS).
- Quotes were obtained from BDS and INDIGO Biosciences; Attagene did not respond to multiple requests for a quote; IonTox eventually responded, but has not produced a quote to date.
- The quotes obtained from BDS and INDIGO Biosciences were for substantially different protocols for carrying out the ER- α and AhR assays.
 - INDIGO Biosciences will not perform the required sample pre-extraction step, whereas BDS offers the option to perform the extraction. It remains unclear which extraction protocol each lab uses and/or requires.
 - INDIGO Biosciences recommended running both the ER- α and ER- β assays in both the Agonist and Antagonist modes for both tests; conversely, BDS recommended running the ER- α instead of the ER- β , and also recommended not doing Agonist and Antagonist Modes.
 - INDIGO Biosciences offered the AhR assay; BDS offered the PAH CALUX and DR CALUX which were stated to be equivalent to the AhR.
 - BDS indicated it held the ISO/OECD TG455 certification for the ER- α assay, and a National Standard Test comparable to EPA Method 4435 for the AhR assay. INDIGO Biosciences indicated that the lab would

- eventually be “ISO-certified” for both assays, but did not provide corresponding method numbers, only their laboratory tech manual.

In summary, OCWD staff was presented with a number of different methodological protocols and variables when seeking quotes for the two required bioanalytical methods. Sorting through the menu of choices is very challenging for those without significant bioanalytical expertise, especially with the minimal guidance and QA/QC criteria provided in the proposed Recycled Water Policy Amendment or otherwise from the State Board. The four recommended commercial laboratories currently focus their services on the pharmaceutical and food industries; they appear unprepared to offer standardized bioanalytical services to analyze recycled water samples at this time. If this situation does not change significantly ahead of the implementation of required bioanalytical tool monitoring, then recycled water project proponents and the commercial laboratories will not have the requisite knowledge and standardized protocols to generate meaningful data with a reasonable level of effort. **As such, we reiterate our strong support for the Final CEC Panel Report recommendation to convene the Bioscreening Implementation Advisory Group with the onset of required bioanalytical monitoring in recycled water.**

While standardization and interlaboratory studies involving bioanalytical tools are documented in the literature, these have typically been small scale-efforts involving a limited number of research laboratories. It is clear that the necessary level of standardization has not yet reached the wider environmental laboratory industry. In comparison, the availability of standardized targeted analytical chemistry monitoring for CECs from commercial and public utility laboratories is far more widespread. In California alone, at least four commercial laboratories (Eurofins, Test America, Weck Labs, and E.S. Babcock) and at least seven public agency labs (OCWD, Orange County Sanitation District, LA County Sanitation District, Santa Clara Valley Water District, City of San Diego, and the Metropolitan Water District of Southern California) are capable of analyzing recycled water samples for CECs using the established liquid chromatography tandem mass spectrometry (LC/MS-MS) technique. Notably, a crucially important “round-robin” interlaboratory comparison study was conducted ahead of the establishment of recycled water CEC monitoring requirements via the 2013 Recycled Water Policy. Water Research Foundation (WRF) Project 4167⁴ featured the evaluation of analytical methods for CEC analysis via an interlaboratory comparison involving 25 different laboratories across three rounds of testing. The study resulted in the identification of method implementation and validation techniques, as well as specific recommendations for sample collection/preservation, analytical techniques, and QA/QC criteria that greatly improved the consistency of targeted CEC monitoring. **We strongly recommend that a similarly structured, wide-ranging interlaboratory comparison study be conducted to help develop and refine the best procedures for conducting the required bioanalytical monitoring in recycled water.** Such an effort is worthy of both State Board and Water Research Foundation funding, and should be a higher priority than attempting to “standardize” or “validate” additional bioanalytical tools via

⁴ Vanderford, B.J., Drewes, J.E., Hoppe-Jones, C., Eaton, A., Haghani, A., Guo, Y., Snyder, S., Ternes, T., Schluesener, M. and Wood, C.J., 2012. Evaluation of analytical methods for EDCs and PPCPs via interlaboratory comparison. Water Research Foundation (formerly American Water Works Association Research Foundation) Report, 4167

additional small-scale studies performed within research labs.

5. Reporting Limits for Health-Based Indicator CECs

Table 1 in Appendix A of the proposed Recycled Water Policy Amendment lists the (minimum) reporting limits (RLs) for the Health-Based and Performance Indicator CECs proposed for required monitoring by potable reuse projects. However, it leaves out a very important stipulation included by the Panel in their Final Report regarding reporting limits (pg. 49, Section 5.4.2, 2nd paragraph): *“Method reporting limits (MRLs) were recommended at a **preferred ratio** of MTL [Monitoring Trigger Level] /MRL is [sic] 10. When this resulted in an MRL that cannot be practically achieved with existing methods (see also Chapter 6), **the Panel recommends setting a MTL/MRL as high as possible, but no less than 2.**”*

For 1,4-dioxane, the newly added health-based indicator for potable reuse projects, the proposed RL is 0.1 µg/L. The only established analytical method that has been demonstrated to reliably achieve such a low RL is EPA Method 522, which was developed specifically for drinking water matrices and used for the USEPA UCMR 3 program. EPA Method 522 requires solid-phase extraction (SPE) followed by analysis via Gas Chromatography /Mass Spectrometry (GC/MS) with Selected Ion Monitoring (SIM). The required SPE step is time-consuming and labor-intensive, requiring large sample volumes and generating solvent waste. Additionally, EPA Method 522 has not been certified by the State Board’s Environmental Laboratory Accreditation Program (ELAP). Given the very low RL requirement and the hierarchy for analytical method selection presented in Section 1.2.1 of Attachment A, the use of EPA Method 522 would effectively be mandated for 1,4-dioxane monitoring.

However, there are other, well-established, and more efficient methods for 1,4-dioxane analysis which reliably achieve RLs of 0.15 – 0.5 µg/L using the purge and trap (P&T) technique for preconcentration before GC/MS analysis. The OCWD Advanced Water Quality Assurance Laboratory has successfully employed a reliable P&T + GC/MS method for 1,4-dioxane analysis for over 15 years. An overview of such methods can be found in a recent paper published in the Environmental Science & Technology journal⁵. The P&T technique allows for much more rapid sample processing than SPE and does not generate solvent waste. With the proposed 1,4-dioxane MTL of 1 µg/L, allowing RLs of 0.15 - 0.5 µg/L would be consistent with the Panel’s recommended minimum MRL/MTL ratio of 2 and be comparable to the ratios of 5-6 proposed for the other health-based indicator CECs (NDMA and NMOR) included in Table 1.

As such, OCWD strongly recommends that the following footnote be added to the Reporting Limit column of Table 1 within Attachment A, consistent with the Panel’s recommendations on RLs:

⁵ Sun, M., Lopez-Velandia, C., & Knappe, D. R. (2016). Determination of 1, 4-dioxane in the Cape Fear River watershed by heated purge-and-trap preconcentration and gas chromatography–mass spectrometry. *Environmental Science & Technology*, 50(5), 2246-2254

Higher reporting limits may be acceptable if those indicated here cannot be practically or efficiently determined on recycled water sample matrices using existing methods, so long as the ratio between the reporting limit and the monitoring threshold limit (RL/MTL) is no less than 2.

For consistency with the footnote, the following bolded text should also be inserted into the beginning of the 2nd paragraph of Section 1.2.1 of Attachment A:

*“Analytical chemistry methods shall be selected ~~in the~~ **subject to** following hierarchical order **and the requirements found within Table 1:**”*

In closing, we commend the State Board for reinitiating a science-based process to inform CEC monitoring requirements for recycled water by reconvening the expert Science Advisory Panel. However, we are concerned that a significant number of important Final CEC Panel Report recommendations have been either ignored or misinterpreted by State Board staff during the drafting of the proposed Recycled Water Policy Amendment. We urge the State Board to modify the current Recycle Water Policy Amendment to be more consistent with the Panel's Final Recommendations, especially with regard to the implementation of required bioanalytical monitoring. OCWD will continue to be a committed stakeholder on CEC and bioanalytical monitoring policy.

Please do not hesitate to contact me at (714) 378-3364 or jdadakis@ocwd.com regarding any of the points we've raised in these comments.

Respectfully,



Jason S. Dadakis
Executive Director of Water Quality & Technical Resources