Development of Quality Assurance Recommendations for the *Ceriodaphnia dubia* Toxicity Test: Background and Rationale for the Study

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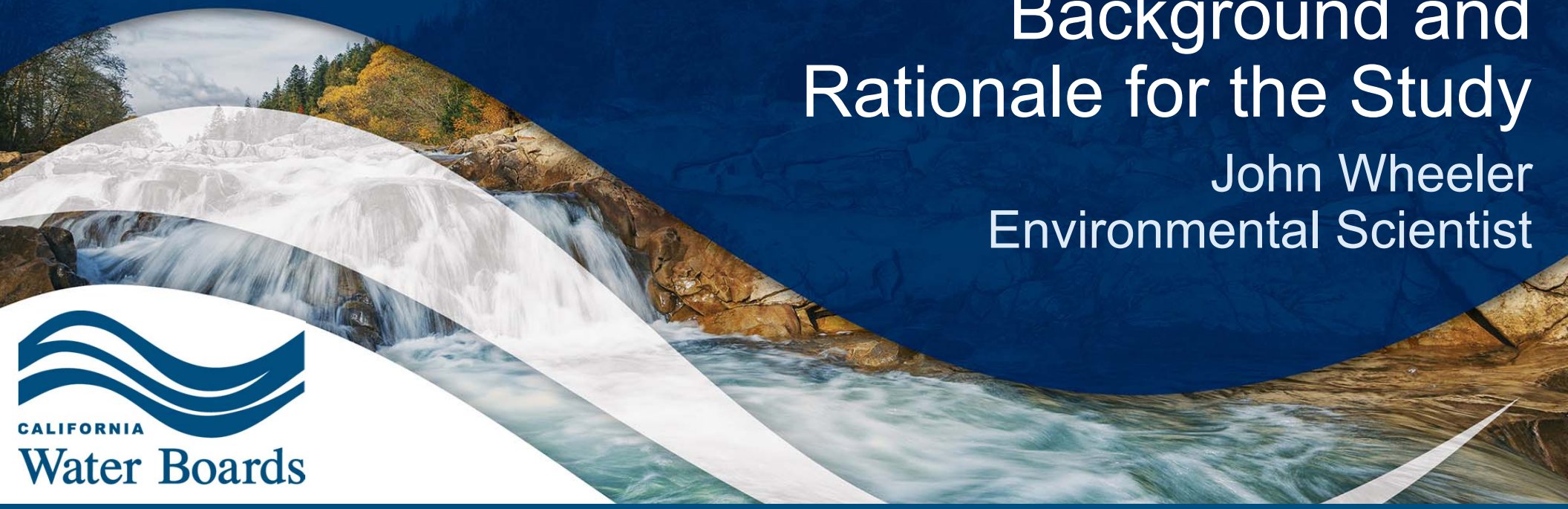

CALIFORNIA
Water Boards

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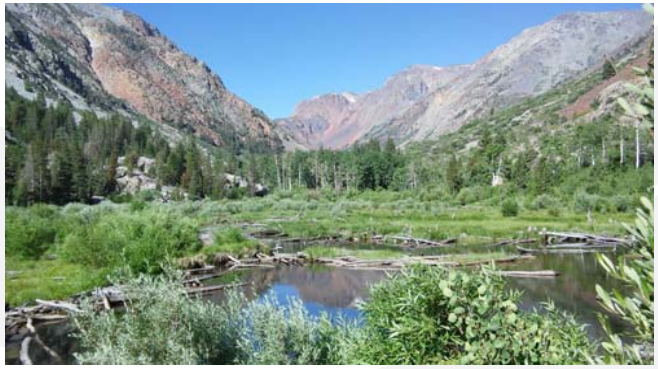
Outline



- Overview of the Toxicity Provisions
- The *Ceriodaphnia dubia* Study:
  - Rationale
  - Purpose
  - Timeline
  - Possible Outcomes
  - Plan

Overview of the Toxicity Provisions

- Statewide Plan to address aquatic toxicity
- Numeric water quality objectives for aquatic toxicity
- Test of Significant Toxicity (TST) statistical approach
- A program of implementation

Test of Significant Toxicity

- A statistical hypothesis test for assessing toxicity test data
- Tests the (restated) null hypothesis:
  - “Do the effluent (IWC) and the control differ by a biologically significant amount?”
- Provides greater confidence in the result
- Common goal: to collect high-quality data
  - Dischargers are incentivized to generate high-quality data
  - State Water Board staff want to have high confidence in the outcome

Program of Implementation – Non-Storm Water NPDES Dischargers

- Instream waste concentration (IWC)
- Species sensitivity screening
- Reasonable potential
- Aquatic toxicity monitoring
- Effluent limitations and targets
- Toxicity reduction evaluation (TRE) requirements

Rationale for the Study

- During public comment period, commenters provided comments on:
  - Appropriateness of using *C. dubia* for compliance
  - Delayed implementation of using *C. dubia* for compliance

Rationale for the Study

Public comments

- *C. dubia* test is a reliable test and is already being used in NPDES permits.
- *C. dubia* is naturally highly variable and can lead to false positive results and violations using the TST when the effluent is not toxic.

Response

- Staff have full confidence in the use of *C. dubia* for regulatory programs.
- Staff Report (Appendix J) analyzed a subset of California laboratories using *C. dubia*
  - Most can meet the acceptable 5% false positive probability of a test "fail" at or below a 10% effect with 10 replicates.
- Conduct a *C. dubia* laboratory quality assurance study to increase the public's confidence in the results.

Purpose of the Study

- Investigate test conditions and factors that can be controlled to reduce within-test variability and improve a laboratory's performance
- Evaluate the consistency and comparability of *C. dubia* toxicity testing among state-accredited laboratories across California
- Guided by a panel of national experts and stakeholder advisory committee

The study **IS**:

- A quality assurance study to determine whether laboratory best practices might be recommended to improve laboratory performance

The study is **NOT**:

- A method validation study to determine whether *C. dubia* should be used in California regulatory programs
- A study to estimate false positive or false negative rates using the TST

Study Timeline

- The Toxicity Provisions were adopted by the State Water Board on December 1, 2020
  - The Adopting Resolution directs staff to initiate the study
- The study will be completed by December 31, 2022
- Staff will report to the State Water Board:
  - Spring 2021 – Information Item on the scope of the study
  - July 2023 – Recommendations Report
- Delayed effluent limitations for *C. dubia* become effective January 1, 2024

Possible Outcomes of the Study

- Staff will report on the findings and recommendations of the study at a State Water Board meeting by July 2023
- Possible regulatory outcomes:
  - Method implementation guidance document
  - Rulemaking that requires all laboratories to make changes to the method implementation
    - For example:
      - Current Test Acceptability Criteria (TAC): 60% of surviving control females must produce three broods
      - Possible outcome of study: Increase the required percentage

Study Plan

Current Funding

- Evaluate existing data
- Review laboratory SOPs
- Review laboratory control charts

Additional Funding

- Laboratory analysis to test promising method controls (e.g., food, laboratory controls, test termination triggers, etc.)

Additional Information:

State Water Board toxicity program page:
https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/tx_ass_cntrl.html

SCCWRP *Ceriodaphnia dubia* Study page:
https://www.sccwrp.org/about/research-areas/additional-research-areas/ceriodaphnia-toxicity-testing-quality-assurance/

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Questions?