C. dubia QA evaluation studyStakeholder Committee Meeting

January 17, 2023

Agenda

- 1. Opening remarks and review of agenda (5 min)
- 2. Review of Progress to Date (5 min)
- 3. Response to the Expert Science Panel conclusions and recommendations from the Baseline Intercalibration Study (20 min)
- 4. Preliminary Scoping for the next phase of the study (45 min)
- 5. Questions from the public (10 min)
- 6. Schedule and Next Steps (5 min)

Stakeholder Advisory Committee

- Katie Fong (SWRCB)
- Amelia Whitson (EPA Region IX)
 - Rochelle Cameron (alternate)
- Veronica Cuevas (RWQCB4)
- Mitch Mysliwiec (Larry Walker Assoc/CASA)
- Jian Peng (Orange County Public Works/CASQA)
- Sarah Lopez (Central Coast Water Quality Preservation Inc)
- Peter Arth (Enthalpy Laboratories)
- Josh Westfall (Los Angeles County Sanitation Districts)
- Annelisa Moe (Heal the Bay)

Overall Project Tasks

- Task 1- Identify potential sources of variability within and among laboratories
 - Compile historical data

 COMPLETED
 - Conduct baseline intercalibration COMPLETED
- Task 2- For potentially largest sources of variability, optimize test conditions and QA parameters to minimize variability TODAY'S DISCUSSION

- Task 3- Evaluate efficacy of test conditions and QA refinements
 - Conduct second intercalibration

Expert Science Panel Findings and Preliminary Recommendations for the Ceriodaphnia dubia Toxicity Test

Selected Slides from December 21, 2022

Preliminary Findings and Recommendations



Preliminary Findings

- Some labs did not pass Test Acceptability Criteria
- Variability in mean neonate production between labs is very large
 - Variability between labs was roughly similar to the variability between labs from historical data
- For labs with consistent quality, the IC25s are reasonably consistent

Additional Considerations for the Study from the Expert Panel

- Finding: Insights about lab performance have been gleaned from historical review and from recent lab testing, but important sources of variability remain to be identified
- Recommendation: Additional time is necessary to study the data further before a complete set of final recommendations can be provided

Focus on Ongoing Culture Health and Performance

- Finding: Method guidance exists for an acceptable brood board culturing procedures
- Finding: [Culturing is the] most likely source of the variability in mean neonate production among labs
- Recommendation: Laboratories need to develop clear, step-wise operating procedures (OP's), documentation and evaluation of brood board health and do not initiate tests when cultures do not meet minimum health standards
- Recommendation: Additional method refinement or optimization should focus on brood boards, particularly variability in age of the female used to start the brood board

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Preliminary Scoping for the Next Phase of the Study

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Two Options for the Next Tasks

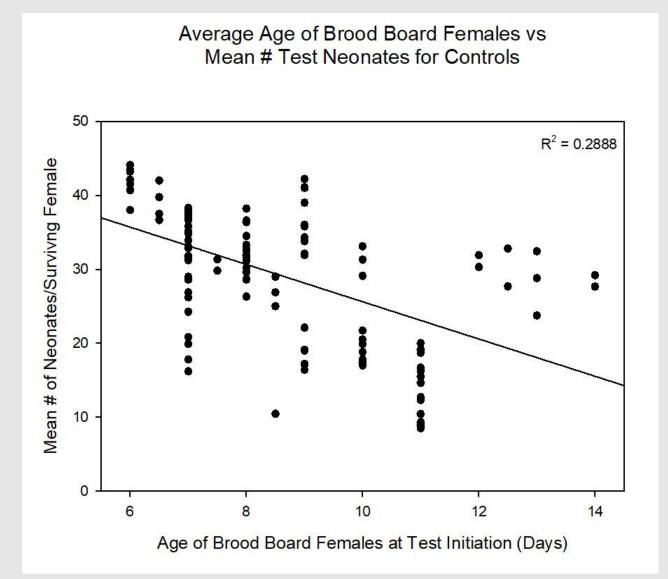
- Option #1: Focus on laboratory training and education regarding culturing and testing
 - Assumes that current guidance is complete and that labs just need additional information to implement consistently
 - Timing allows for a second intercalibration following training and education
- Option #2: Focus on the one variable that came out of the first intercalibration - Age of female at test initiation
 - Directed testing of females of different ages to quantify variability
 - Timing does not allow for a second intercalibration using the optimized method

Option #1: Laboratory Training and Education

- Series of group meetings among laboratories with a goal of mimicking techniques from the best performing laboratories
 - Curriculum yet to be defined
- Techniques identified as being potentially beneficial to improving laboratory performance will be included as revised methods during the second interlaboratory study
- May include audits during second intercalibration to assess implementation success
- Since unquantified, we won't know which technique(s) is the most important

Option #2: Age of Female Used to Initiate Test

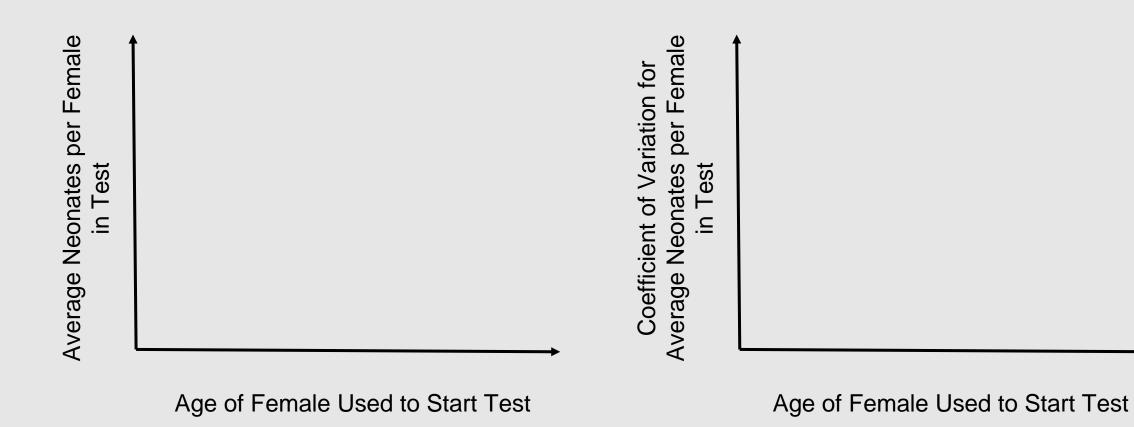
- EPA Method guidance requires females should be <14 days old
 - First intercalibration ranged from 6 to 14 days old
- Intercalibration showed that average neonate production decreased with increasing age of female
- This may not be the only factor causing variability



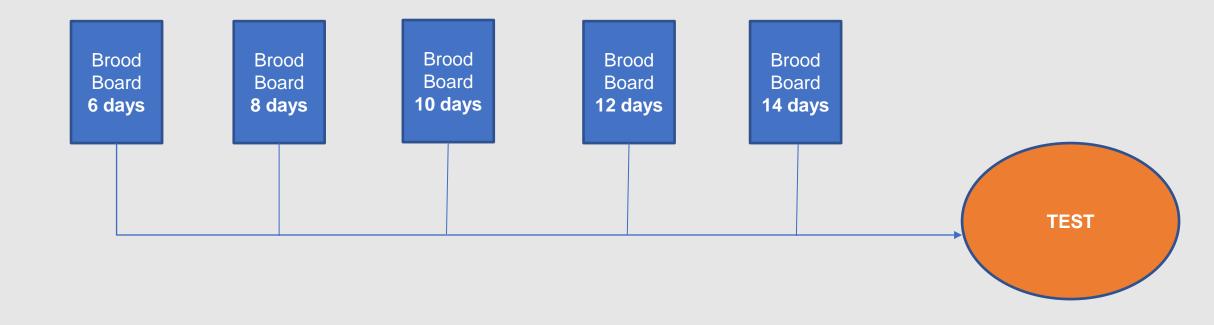
Directed Testing for Quantifying Variability in Age of Female Used to Initiate Tests

- Use only a single lab to control all other sources of variability
 - Likely one of the more consistent laboratories in first intercalibration
- Quantify neonate production in brood board females of different ages
 - Two alternative study designs (slides to follow)
- Utilize unspiked dilution water
 - May include a spiked sample if resources allow
- Repeat multiple times for replication

Expected Graphics

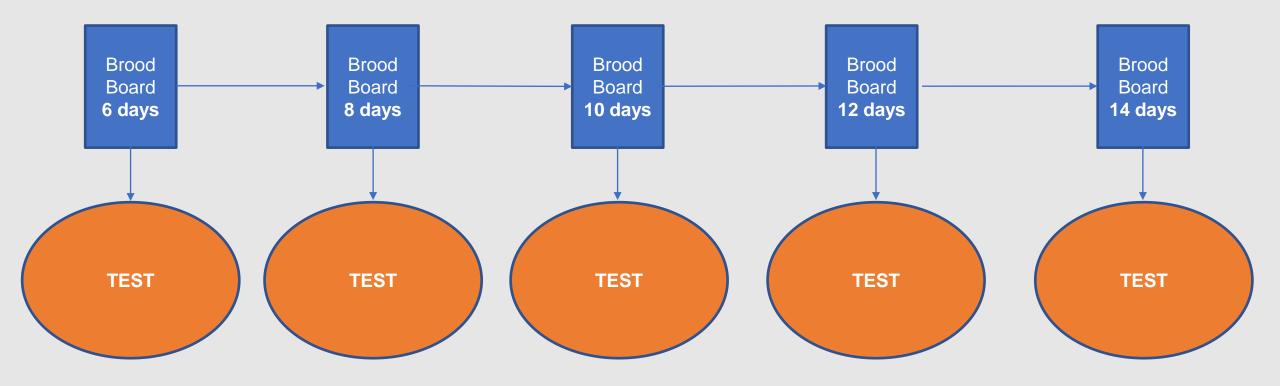


Alternative Design A: Multiple Brood Boards 2 days Apart



- One lab, repeat three times
- Testing will require 8 weeks minimum

Alternative Design B: One Brood Board Testing Two Days Apart



- One lab, repeat three times
- Testing will require 8 weeks minimum

Two Options for the Next Tasks

- Option #1: Focus on laboratory training and education regarding culturing and testing
 - Assumes that testing guidance is complete and that labs just need additional information to implement consistently
 - Timing allows for a second intercalibration following training and education
- Option #2: Focus on the one variable that came out of the first intercalibration - Age of female at test initiation
 - Directed testing of females of different ages to quantify variability
 - Timing does not allow for a second intercalibration using the optimized method

Next Steps

- Summarize recommendations from today for the Expert Science Panel
- If option #1: training and education
 - Prepare a curriculum and a schedule
 - Prepare a written plan for second intercalibration
- If option #2: Age of female testing
 - Select laboratories and delineate final study design
 - Prepare a written plan for directed testing
- Either option will require rapid response to meet SWRCB timelines