Science Panel Meeting for *Ceriodaphnia dubia* Quality Assurance Study

Minutes of Meeting #2

Held remotely on Monday April 12, 2021, 11:00 AM to 12:00 PM

List of Participants:

Facilitators:

Ken Schiff, Alvina Mehinto (SCCWRP)

Expert Science Panel:

Toxicologist, Industry - Howard Bailey (Nautilus Environmental, Canada)
Toxicologist, Government -Teresa Norberg-King (US Environmental Protection Agency)
Toxicologist, Academic - Robert Brent (James Madison University)
Quality Assurance - Leana Van der Vliet (Environment and Climate Change, Canada)
Biostatistician - John Bailer (Miami University)

Invited speakers:

Sarah Lopez (Central Coast Water Quality Preservation Inc.) Veronica Cuevas (Veronica Cuevas, Los Angeles RWQCB4)

There were 40 attendees in the virtual public audience.

Agenda Item #1 – Opening Remarks and Review of the Agenda

Ken Schiff of SCCWRP called the meeting to order at 11:02 AM and welcomed the attendees. The Science Panel members provided brief self-introductions.

Agenda Item #2 – Minutes of Science Panel Meeting #2

Howard Bailey motioned to approve the previous meeting minutes, and Robert Brent seconded. All panel members voted aye to approve the minutes. These approved minutes will be posted to the project website.

Agenda Item #3 – Perspectives from Select Stakeholders

Two presentations were given by Stakeholder Committee members, Sarah Lopez (Central Coast Water Quality Preservation Inc.), and Veronica Cuevas ((Los Angeles RWQCB4). Sarah's presentation provided further context for how *C. dubia* toxicity test results are used in regulatory programs for agriculture. Until recently, the survival endpoint was so impacted that the reproduction endpoint was not used. As survival has increased, the reproduction endpoint has become an important and sensitive marker for toxicity testing. It is critical for this study to help define clear data quality objectives and procedures for this toxicity test as the regulatory impacts can be significant for the agricultural community. Veronica shared the perspective of the State Waterboard. They believe the toxicity data provides valuable information that water chemistry alone cannot provide. They are hopeful this study will lead to greater acceptance of the test method by the regulated community once it is optimized.

Agenda Item #4 – Expert Science Panel Feedback on the Written Draft Study Workplan

Ken Schiff summarized the workplan development and review process, including the previous Stakeholder and Science Panel meetings. The draft workplan has 5 main tasks: 1) Create a governance structure; 2) Analyze historical data and lab techniques; 3) Conduct lab testing to optimize techniques; 4) Evaluate the revised lab technique guidance via split-sample testing; and 5) Produce a final report with recommended guidance. The workplan details Tasks 1 and 2, and further modifications will include more details for Tasks 3-5.

The Science Panel met in a closed session prior to the public meeting to review the workplan and discuss their suggested revisions. Each panel member will provide their individual comments to Ken Schiff by the end of the week. Overall, they found the workplan to be acceptable after major revisions. The main revisions discussed include:

- Revise the workplan to follow the format of a QAPP and provide additional details such
 as clear definitions of key terms, how to quantify variability, specific measurements used,
 procedures and processes to compare the potential factors and how they impact
 variability. It may be appropriate to initially provide the QAPP details for Tasks 1 and 2,
 with a modified or new document for Tasks 3-5 later.
- There are certain methods in the original test design that are meant to be flexible to improve relevance/representativeness. This study should not necessarily provide standardization for some of these methods where flexibility is indicated.
- The list of factors/data types in Table 4 may be an incomplete list. It is important to ask
 the labs for their insight about methodology and what each has done to improve test
 performance in their own labs.
- It is critical to define and understand common components of variability versus specific issues or factors that may influence variability.
- Clarify terminology (i.e., sample size as the number of experiments versus number of animals in a replicate).
- Provide a more detailed description of the simulation study.
- Think carefully about what information to record and gather. Any information not measured or recorded cannot be accounted for in the historical data analysis (i.e., laboratory technician experience).
- It is important to collect as much of the raw data as possible to allow for more thorough analysis, compared with just summary results.
- The statistical methods need to be more carefully described in the workplan.
- Before the CASA proposal (Appendix B) and split-sampling is considered, there need to be detailed discussions to explore options for test design based on the historical data analysis (i.e., before-after or before-after-before testing). Additionally, variables involved in split sample testing (i.e., shipping, holding times, containers, etc.) may not be relevant to normal test variability and could impact the results of the study.
- It is necessary to quantify how much variability remains after optimization of the protocol, as well as where the variability is found (i.e., CV in controls may be the same between two labs but the organism sensitivity may be vastly different, which can still impact the toxicity test outcome).

- The introduction needs more details regarding the specific issues the study intends to address as well as information on what, if any, factors have already been investigated for their impact on variability, or which factors are expected to be important.
- Interviews with the laboratories will be critical for finding more specific differences in methodology and general practices which could be significant.
- The Science Panel would like to conduct a laboratory group meeting(s) to discuss lab techniques.
- It may be better to evaluate the historical data with a simpler subset of results before getting more complex (i.e., compare the variability in IC25 results from reference toxicants versus the variability in controls from 1-2 labs).
- Clearly define what criteria will be met to denote a difference in variability (qualitatively and quantitatively).

Ken Schiff summarized the comments into three major categories:

- 1. The workplan is acceptable with required major revisions.
- 2. The CASA proposal (Appendix B) should not be considered until after the Task 2 data is collected and analyzed, and the Science Panel has had time to review the results.
- 3. Revise the workplan to provide clarifications, more details, QAPP, and include meetings between the labs and the Science Panel.

Key Dates:

April 27 (TBC): Approval of workplan by the Science Panel May 1: Submit final workplan to State Waterboard

The meeting was adjourned at 12:04 PM.