C. dubia QA evaluation study

Expert Science Panel Meeting

Friday June 24, 2022

Agenda

1. Opening Remarks and Review of the Agenda (5 min)
2. Minutes of Expert Science Panel Meeting #5 (5 min)
3. Baseline Testing Plan (15 min)
4. Stakeholders Perspectives (25 min)
5. Panel and Stakeholders Discussion (50 min)
6. Schedule and Next Steps (10 min)

Baseline Study Plan

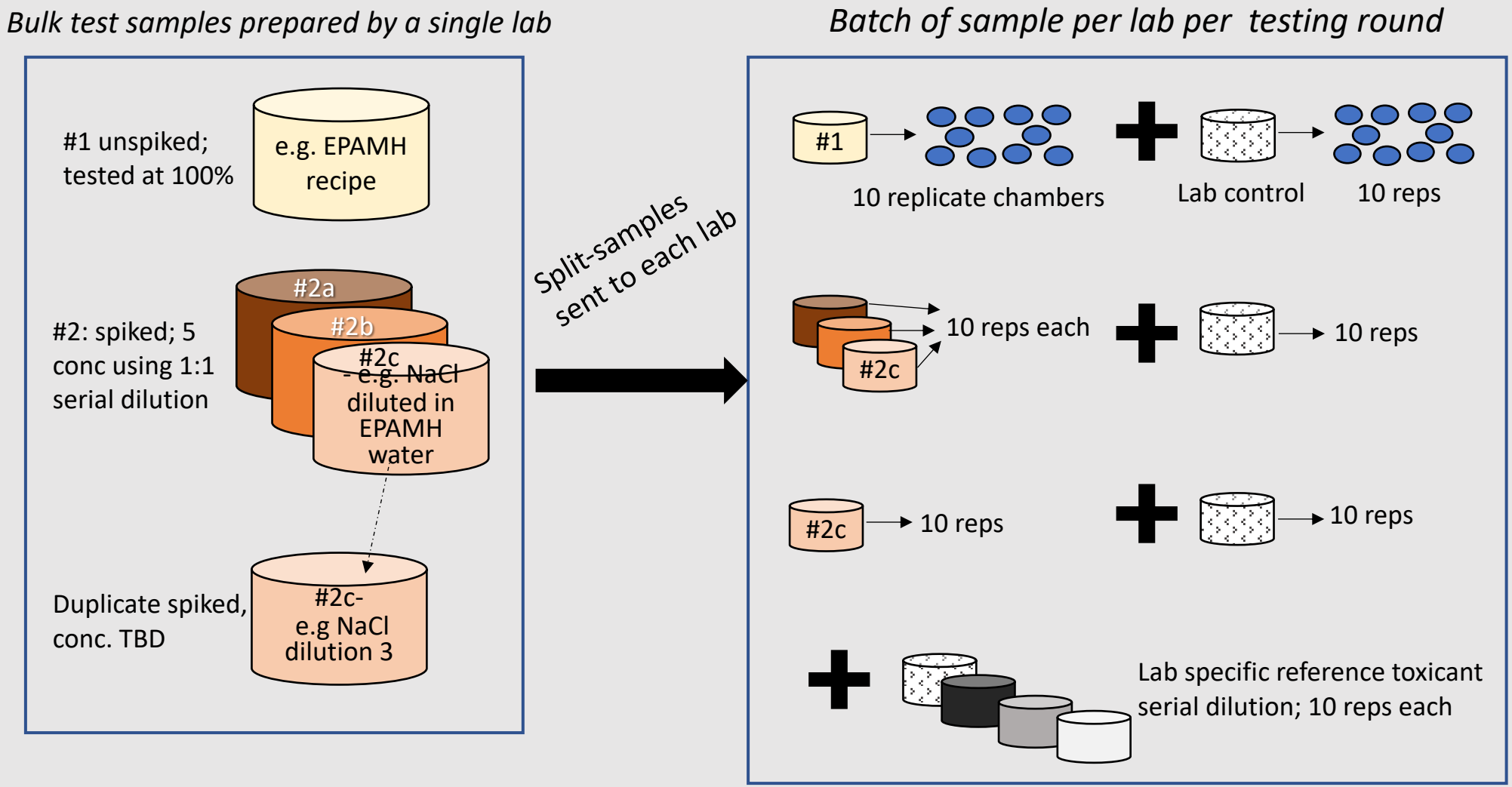
Progress to date:

- Draft study plan produced and reviewed by stakeholders
- Created bench sheets and data submission forms
- Contacted laboratories to confirm participation and collect pricing information

Goal for today is to discuss key study elements to finalize the study plan and develop detailed QAPP

- Testing option
- Specific samples to test
- Data requirements
- Key data outputs/products

Conceptual Study Design



Three Testing Options

No. of test batches	No. of test sample	No. of dilutions per test sample
Testing option 1		
3	1 unspiked	1
	1 spiked	5
	1 duplicate	1
Testing option 2		
2	3 unspiked	1
	1 spiked	5
	1 duplicate	1
Testing option 3		
2	2 unspiked	1
	1 spiked	5
	1 duplicate	1

Each option will generate a minimum of **7** lab control datasets

Number determined based on assessment of the mean control response (# neonates/female) per lab and statistical determination of the number of samples required to ensure that mean response for the study falls within the historical range (+ or – 5 neonates)

Test Samples

Unspiked sample

- same water recipe tested multiple times or a different recipe per test batch
- all tested at full strength (i.e., 100%)

Spiked sample

- sodium chloride based on previous recommendations from the Panel
- tested at 5 conc. using a 1:1 serial dilution

Duplicate sample to be determined by SCCWRP

- unspiked duplicate as determined above
- or duplicate of one of the spiked sample dilution

Study Design – Clarifications

- This is not a false positive study
- Spiked sample will be tested using 5 conc (using a 2-fold serial dilution)
- Each test batch includes the lab's own reference toxicant (i.e., not provided by SCCWRP), tested at 5 concentrations + lab control
- Split-samples provided by SCCWRP will be tested with a separate laboratory control. Sharing control for multiple samples is not allowed (except for the 5 dilutions of the spiked sample)
- Chemistry samples will be collected on day of test initiation and shipped to SCCWRP overnight. Ion analyses will be performed within 10 days of collection. Samples of the lab's dilution water, and reference toxicant stock will be archived at SCCWRP.

Three Testing Options

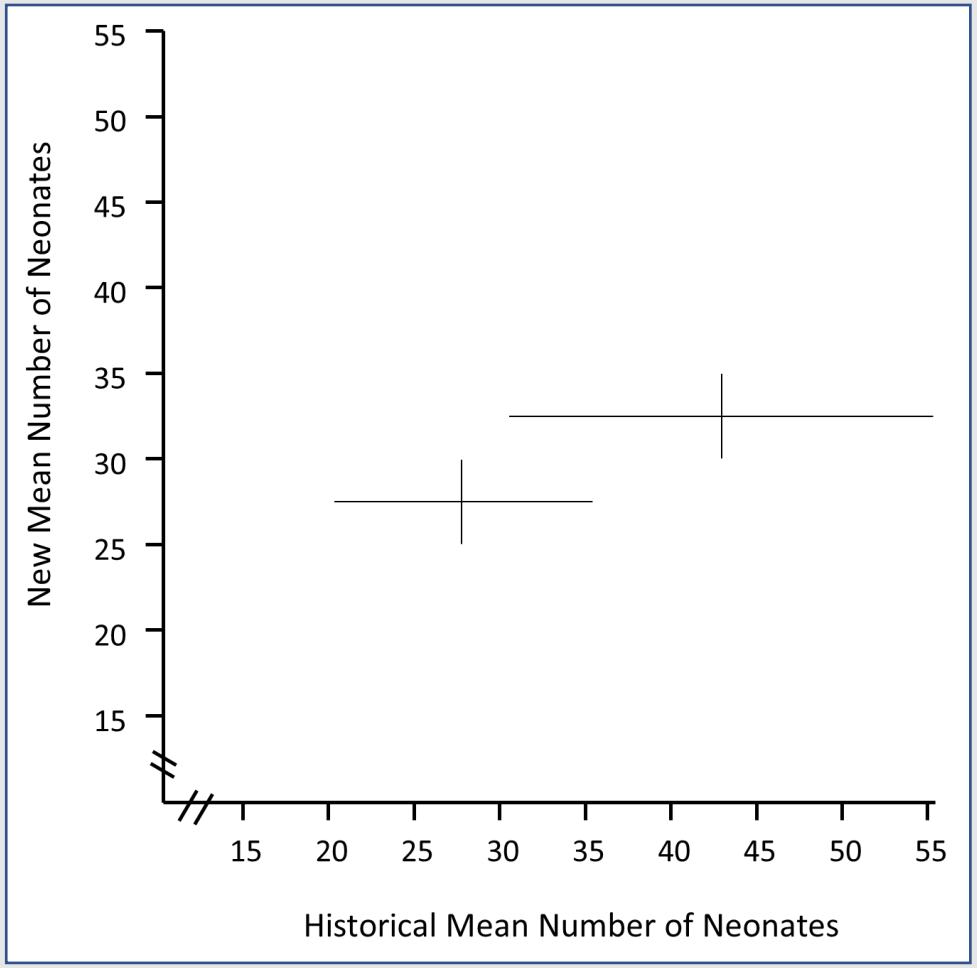
* 13 participating labs

Test sample type	No. of test batches	No. of split samples	No. of dilutions per split sample	Total number of split samples	Estimated cost
Testing option #1					
Unspiked	3	1	1	273	$225K
Spiked		1	5		
Duplicate		1	1		
Testing option #2					
Unspiked	2	3	1	234	$210K
Spiked		1	5		
Duplicate		1	1		
Testing option #3					
Unspiked	2	2	1	208	$180K
Spiked		1	5		
Duplicate		1	1		

Examples of Key Graphics

Comparison of ‘historical’ vs ‘current study’ variability in mean neonate production in lab controls when conducted under select test constraints.

Data not real!



Example graphic showing reduced variability in potency estimate.

Would only be applicable for labs using sodium chloride as their ref tox.

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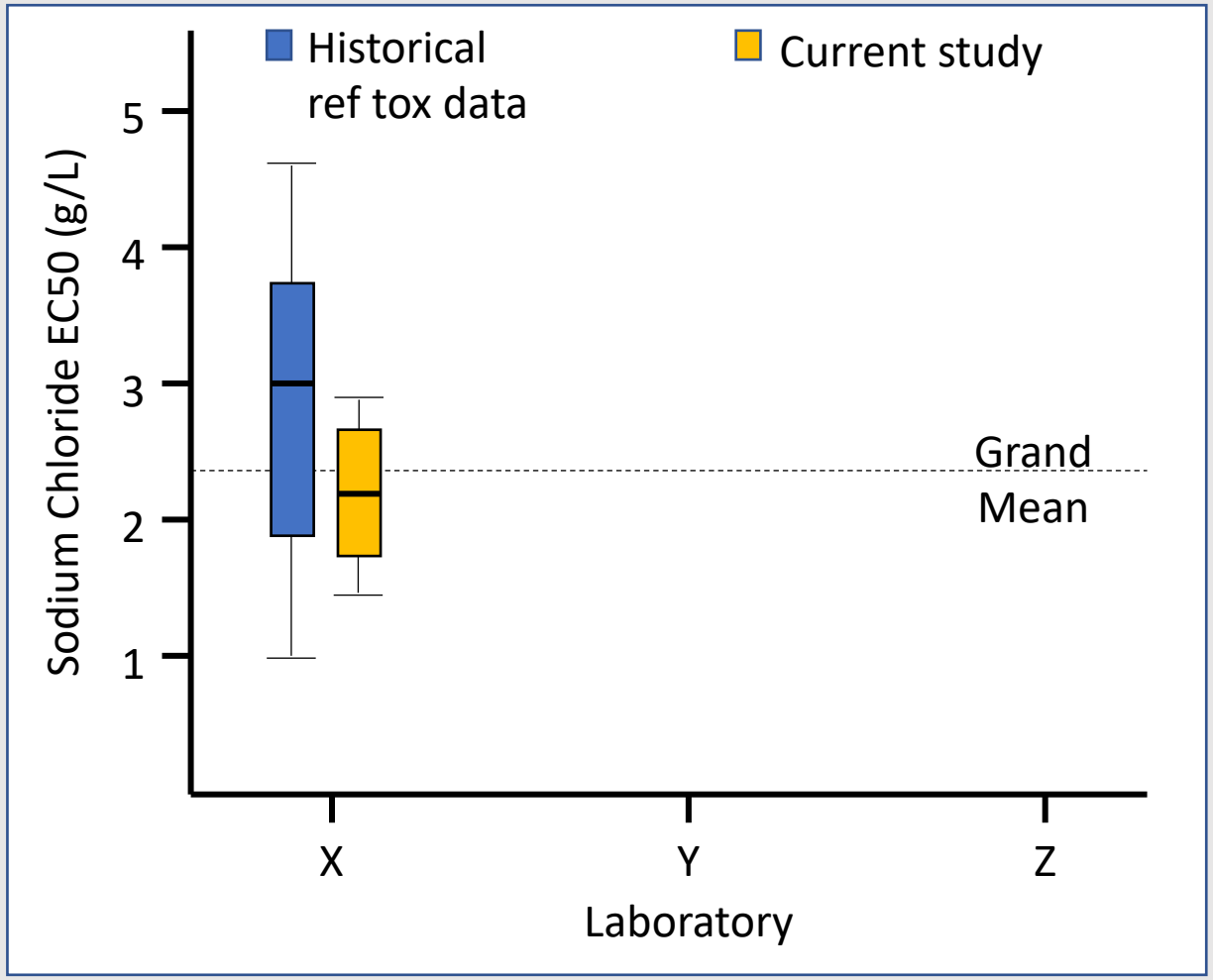


4. Stakeholders Perspectives (25 min)

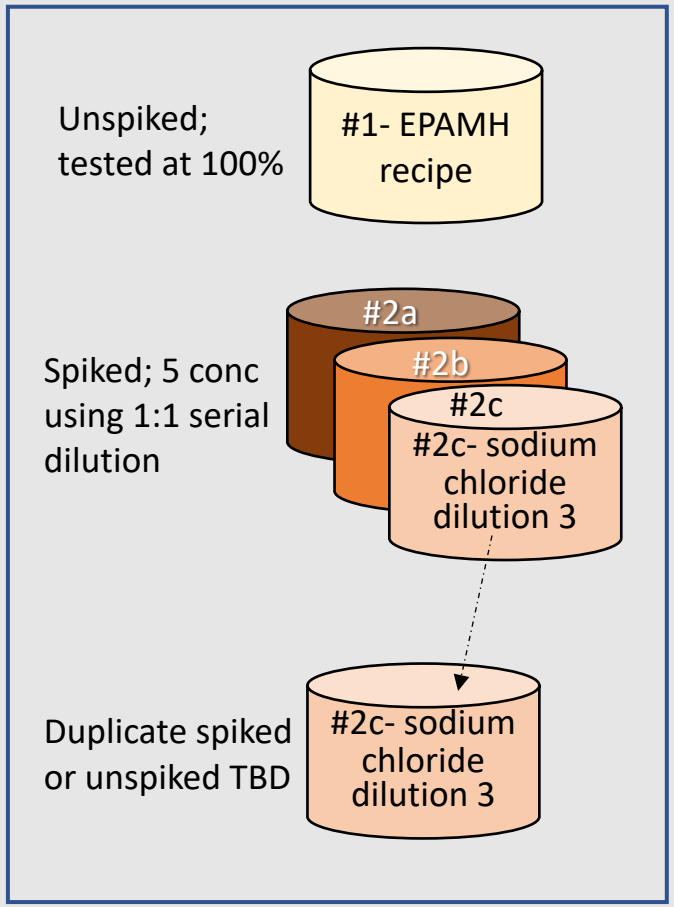
5. Panel and Stakeholders Discussion (50 min)

Discussion Points for Today

- Recommended testing option
  - i.e., number of split samples per batch per lab, and number of test batches
- Specific samples to test
- Data requirements
- Key data outputs/products

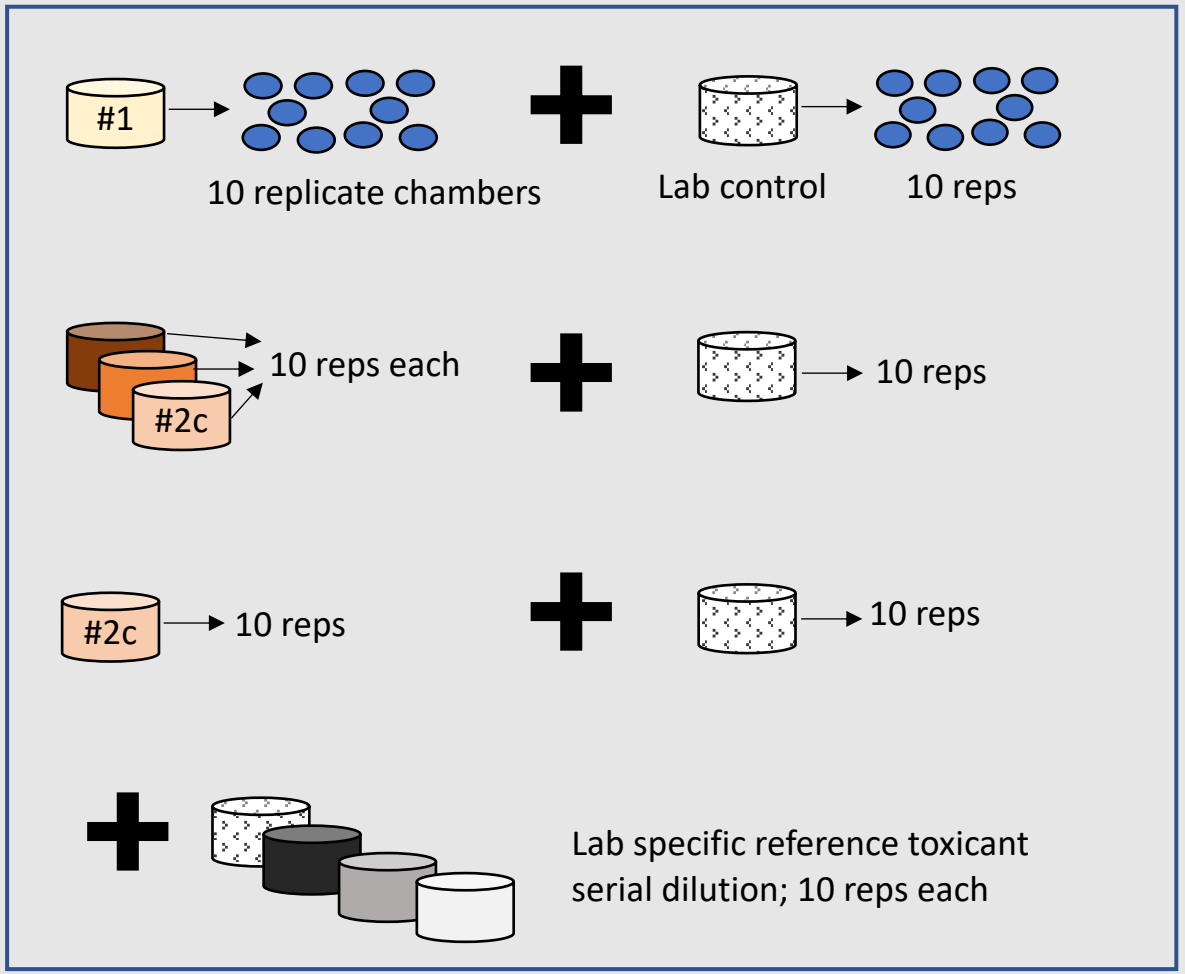
Conceptual Study Design

Bulk test samples prepared by a single lab



Split-samples sent to each lab

Experimental set up for each testing batch per lab



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Testing Options and Samples

How many batches?

- Two or three?
- Should samples be the same for each batch?

How many unspiked samples?

- one water recipe tested multiple times or different recipe per test batch

Is one spiked sample/one chemical sufficient?

6. Schedule and Next Steps (50 min)

Upcoming Activities

- July ~~11~~ 15: SCCWRP will send the revised study plan and the draft QAPP to stakeholders and Science Panel. Final comments are due July 21 at 5pm PDT.
- July (before July 12): ESP closed session to provide recommendations on the study design
- July (week of ~~18 or~~ 25): Meeting with participating laboratories. SCCWRP will review testing requirements and provide training for data collection/submission.
- July xx (or 1st week of August): ESP closed session to review and approve the study plan and QAPP
- August – September: C dubia toxicity tests (2 or 3 batches)
- October xx (no later than Oct 10) Deadline for data submission