



WATER REUSE

CALIFORNIA

Bioanalytical Screening of Recycled Water

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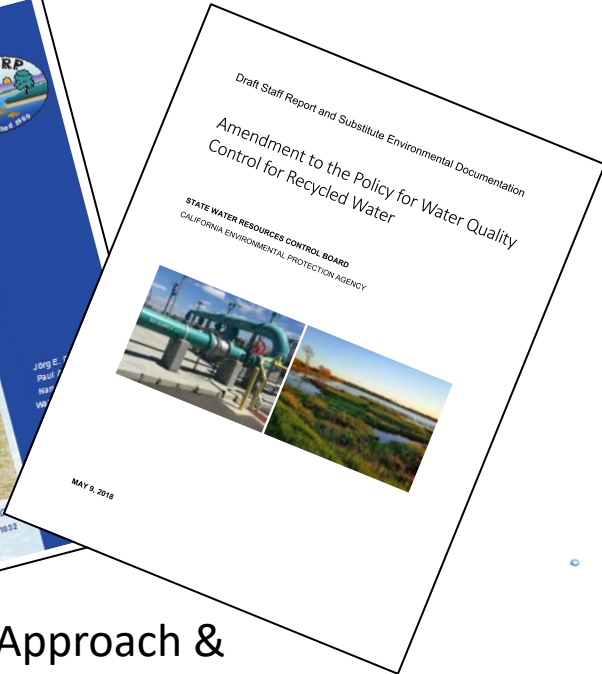
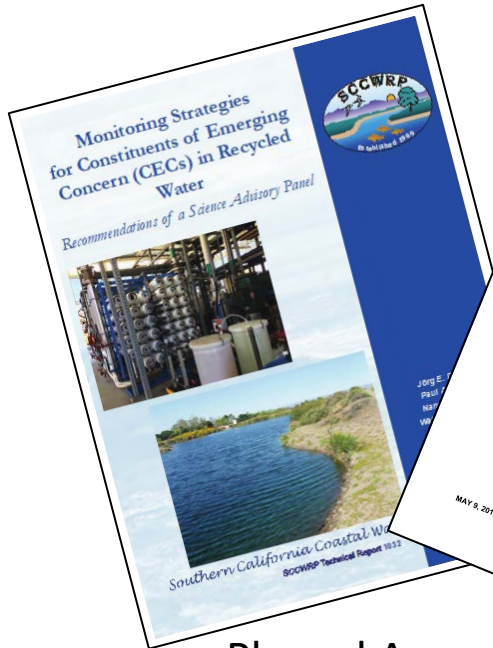


Topics for Discussion

- Key differences between CEC Report and Draft Recycled Water Policy
- Standardization / validation of bioassays methods in recycled water
- Suggested approach for next steps with bioassay monitoring



KEY DIFFERENCES BETWEEN EXPERT PANEL REPORT AND RECYCLED WATER POLICY



Phased Approach &
Response Actions



Both Panel and Draft RW Policy Outline a Phased Approach

Expert Panel

Phase 1

3-5 year data collection & research
No response action requirements

Phase 2

1-year pilot evaluation of
bioassay framework

Phase 3

Implement at
full-scale

Both Panel and Draft RW Policy Outline a Phased Approach

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**On-going guidance from Board-
convened Bioanalytical Advisory Group
(experts, Board staff, industry, etc.)*

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Expert Panel

Phase 1

3-5 year data collection & research
No response action requirements

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1-year pilot evaluation of
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Phase 3

Implement at
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Draft RW Policy

Initial

Monitoring

1-year duration

Response actions
per Table 10

Baseline

Monitoring

3-year duration

Response actions
per Table 10

Standard

Operations

On-going

Response actions
per Table 10

Both Panel and Draft RW Policy Outline a Phased Approach

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*The CEC Panel's approach
is more deliberate*

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Response actions
per Table 10

Response actions
per Table 10

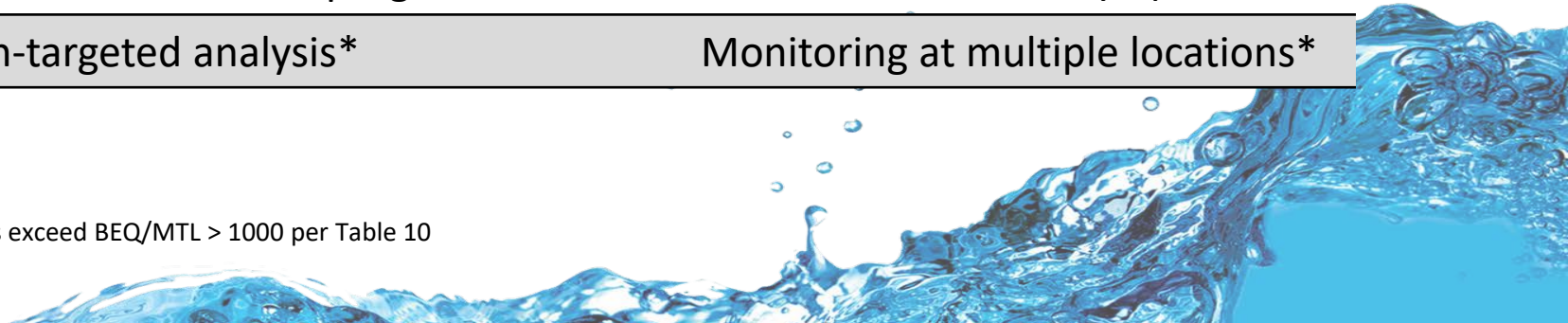
Response actions
per Table 10

Response actions required by RW Policy*

- Immediate resampling and analysis if BEQ/MTL > 10
- Contact Regional and State Board to discuss additional actions
- Additional actions may include *but are not limited to*:

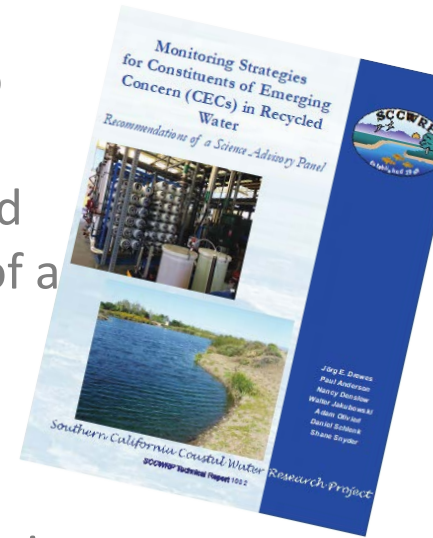
Targeted analytical monitoring	Toxicological studies*
Higher frequency bioassay monitoring	Engineering removal studies*
Source identification program	Modification of facility operation*
Non-targeted analysis*	Monitoring at multiple locations*

* If bioassay results exceed BEQ/MTL > 1000 per Table 10

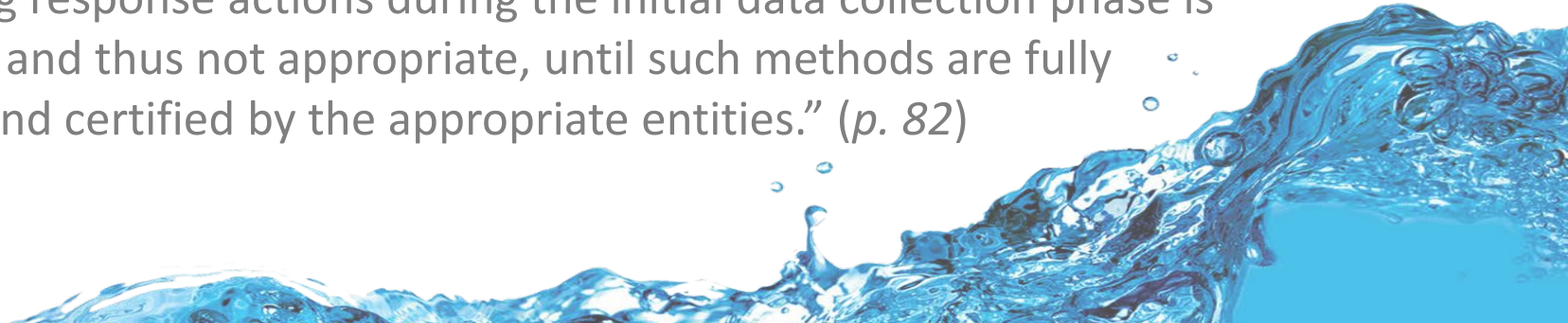


Panel: Response Actions are Premature

“While the Panel has outlined a process to interpret and respond to 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.” (p. ix)



“...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.” (p. 82)



Panel Recommendation: Bioscreening Implementation Advisory Group

- Composed of Water Board, bioassay experts, utilities
- Help guide utilities and Water Board through data collection
- Help specify protocols for sampling, extraction, measurement and data reporting
- Provide guidance for interpreting bioanalytical monitoring results
- **Use of Advisory Group not included in RW Policy**



STANDARDIZATION / VALIDATION OF BIOASSAY METHODS IN RECYCLED WATER

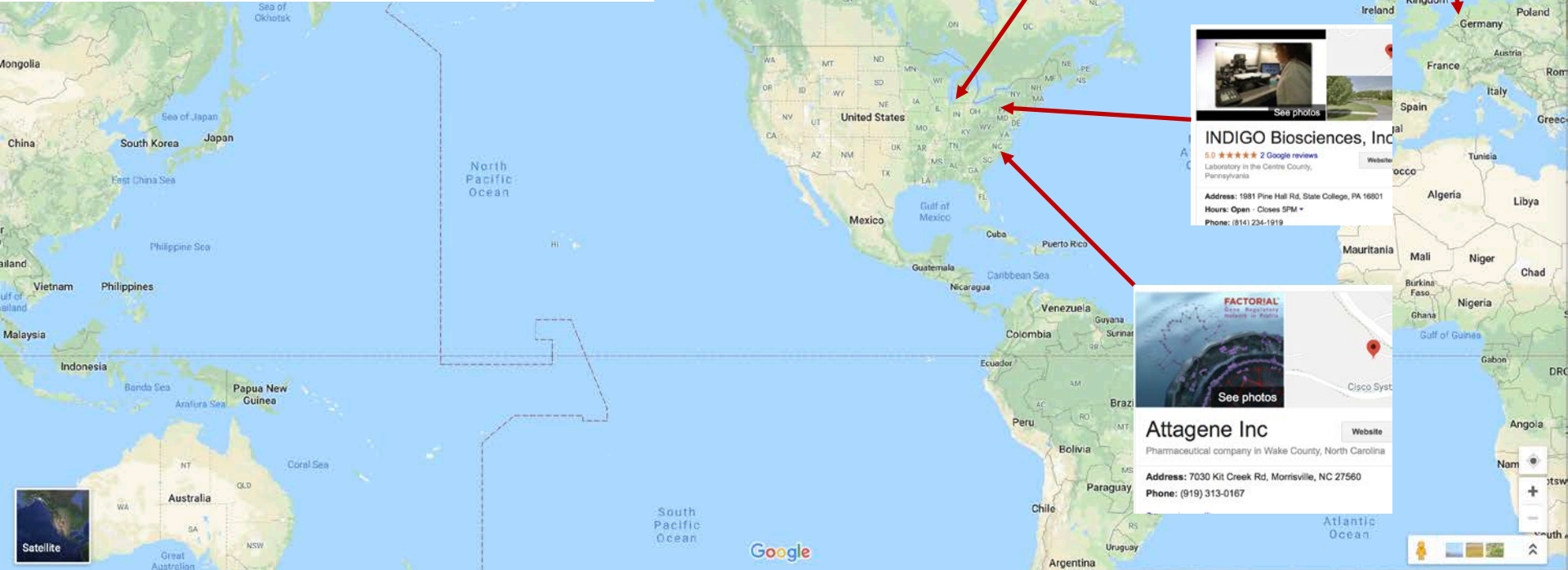


Method Consistency Challenges

- Limited availability of labs – 4 listed in Final CEC Expert Panel Report
 - BDS (Netherlands), INDIGO Biosciences, IonTox, and Attagene



Location of the Four Labs Listed by the CEC Panel



IONTOX
Biotechnology company in Kalamazoo, Michigan
Address: 4717 Campus Dr, Kalamazoo, MI 49008
Hours: Open - Closes 5PM +
Phone: (269) 372-3995

BDS
BioDetection Systems
Home About Services Products Applications International
Contact information
Directions
International partners
General
BioDetection Systems Inc.
Science Park 450
1208 9th Amsterdam
The Netherlands
Tel: +31 (0)20 4390 790
Fax: +31 (0)20 4396 757

INDIGO Biosciences, Inc
5.0 ★★★★★ 2 Google reviews
Laboratory in the Centre County, Pennsylvania
Address: 1981 Pine Hill Rd, State College, PA 16801
Hours: Open - Closes 5PM +
Phone: (814) 234-1919

Attagene Inc
Pharmaceutical company in Wake County, North Carolina
Address: 7030 Kit Creek Rd, Morrisville, NC 27560
Phone: (919) 313-0167

Method Consistency Challenges

- Limited availability of labs – 4 listed in Final CEC Expert Panel Report
 - BDS (Netherlands), INDIGO Biosciences, IonTox, and Attagene
- They are using different approaches
 - Early 2018 OCWD inquiry related to research study: BDS and INDIGO proposed different methodological recommendations



Method Consistency Challenges

Policy-Required Bioanalytical Test	Indigo (Pennsylvania)			
	Extraction	Bioanalytical Test Offered	Mode	Certifications Indicated by Lab for Method
ER- α	Other lab	Recommended ER- α and ER- β	Recommended Agonist and Antagonist Modes For Both Tests	Said lab will be ISO certified for the 2 bioassays. Methods #s unclear, sent their Tech Manual
AhR		AhR		

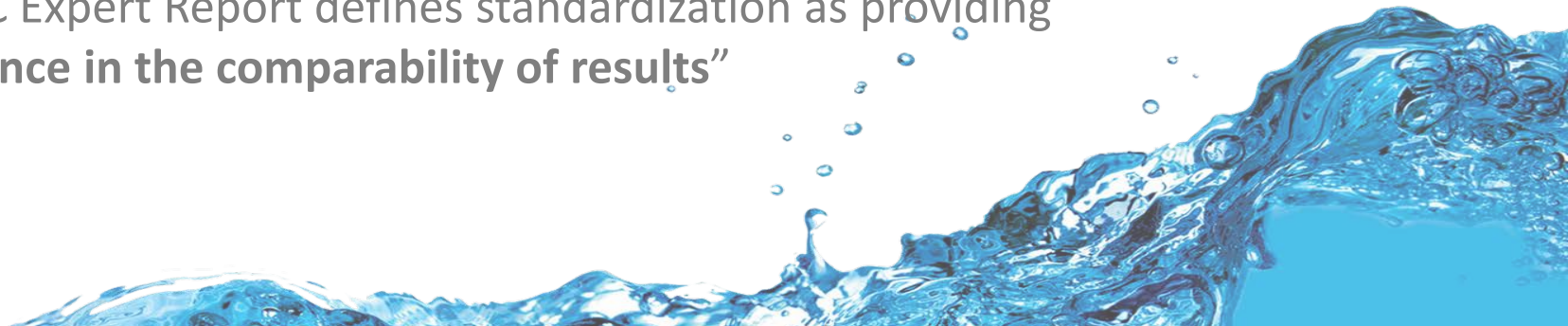
BDS (Netherlands)			
Extraction	Bioanalytical Test Offered	Mode	Certifications Indicated by Lab for Method
BDS or other lab	ER- α (Recommend this over - β)	Recommended NOT doing Agonist and Antagonist Modes	ISO/OECD TG455
	PAH CALUX		National Std test comparable to EPA 4435
	DR CALUX		

*Note: Attagene did respond to multiple requests for a quote
IONTOX responded but not yet with quote*



Method Consistency Challenges

- Limited availability of labs – 4 listed in Final CEC Expert Panel Report
 - BDS (Netherlands), INDIGO Biosciences, IonTox, and Attagene
- They are using different approaches
 - Early 2018 OCWD inquiry related to research study: BDS and INDIGO proposed different methodological recommendations
 - Selection from their menu requires bioanalytical expertise
- Final CEC Expert Report defines standardization as providing **“confidence in the comparability of results”**



Additional Standardization Challenges

- State Board QA/QC Requirements
 - Draft Policy 1.3.2: MDL studies and RL verification shall be submitted to State Board for approval prior to beginning sampling
 - Recycled water producer should not be responsible to maintain the lab's QC documentation; lab oversight should be done by other party (typically ELAP)
- Lab certification
 - Draft Policy 1.3.1: Lab providing bioanalytical analysis 'shall be accredited by ELAP for whichever method is selected' and says State Board must be consulted to determine appropriate method.
 - ELAP not possible; different certifications appear available



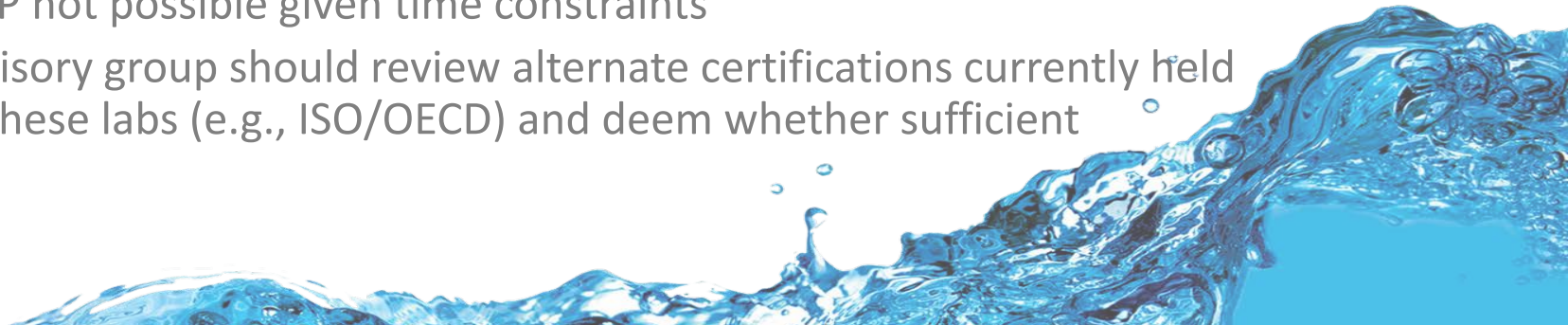
Panel Recommendations to Address Standardization Challenges

- Final CEC Expert Report described **planned SWRCB/WRF study on “Standardizing Bioanalytical Tools...for Recycled Water”** (pg. 71) to start mid-2018 and *synchronize* with the state-wide monitoring effort
- This research team should contact the 4 labs and develop a standardized, consistent approach (SOP) to be used for utility monitoring
- Utility data can then feed into the research study
- Study will feature an inter-laboratory comparison



Suggested Approach to Address Standardization Challenges

- Reporting limit data submission
 - CEC Expert Panel recommended convening *Bioscreening Implementation Advisory Group* (“bioanalytical advisory group”) to guide utilities through the initial round of testing
 - Advisory group should ensure lab(s) submit necessary and sufficient information regarding RLs/MDLs
- Lab certification
 - ELAP not possible given time constraints
 - Advisory group should review alternate certifications currently held by these labs (e.g., ISO/OECD) and deem whether sufficient



Relationship Between Response Actions and Standardization

- Numeric limits tied to response actions are premature for methods that have not been fully standardized / validated

“The Panel further recommends that 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.”

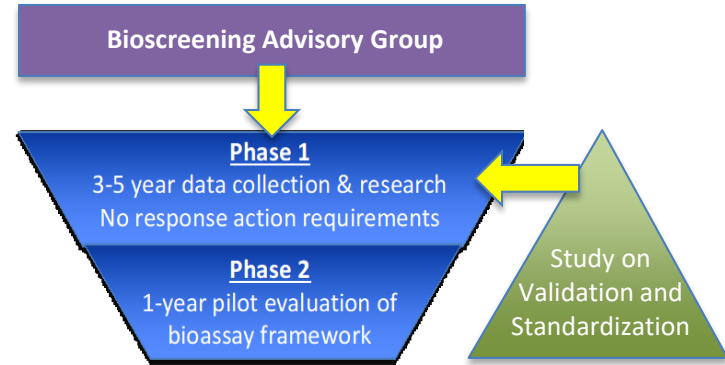


SUGGESTED APPROACH FOR NEXT STEPS WITH BIOASSAY MONITORING



Suggested Approach: Follow Panel Recommendation

- Convene Bioscreening Implementation Advisory Group
- Complete State Board standardization / validation study
- Implement approach Panel recommended
 - Phase I collect data and develop guidance
 - Phase II conduct pilot screen and evaluate results with Advisory Group



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- Implement Phase III during next update of CEC and Recycled Water Policy
 - Include response actions at that time (as applicable)

Phase 3
Implement at
full-scale

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