

Where No Accreditation Program Has Gone Before: Microplastics

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California Environmental Laboratory Accreditation Program (ELAP)

- We are a multidisciplinary team of chemists, environmental scientists, and microbiologists
- Investigate fraud and inappropriate laboratory practices
- Offer technical expertise in laboratory and regulatory science
- Accredite over 600 laboratories that generate data for California regulatory agencies



Overview



Shared Responsibilities in California



Microplastics Case Study



TNI and Accreditation of New Methods

Shared Responsibilities

Regulators

- Determine what their objectives are
- Weigh the advantages and disadvantages of each method available to them
- Request methods be offered for accreditation

ELAP

- Accredite laboratories for methods that are used for regulatory purposes
- Consult with Regulatory Agencies
- Advocate for laboratories and data quality

Laboratories

- Generate data for regulatory decision making
- Uphold scientific integrity
- Provide critical feedback regulators and ELAP

Maybe Wishful Thinking...

Expectations



Reality



CA ELAP's Role

- Regulators do not always understand laboratory science or interests
- Laboratories do not always understand regulatory science
- The job often falls to ELAP to be the translator
 - With help from our Technical Advisory Committee

Microplastics Case Study

- Accreditation of new methods starts with three items
 - A data user/client requesting accreditation
 - An SOP
 - An understanding of method performance characteristics
- We have all three of those for microplastics measurement
- However, the completion of accrediting a new method involves a number of policy decisions
 - **Goal of my talk: Use microplastics as a case study to illuminate those decisions**

TNI and Accreditation of New Methods

- Not all projects can follow that of Microplastics
 - Not all will have funding for this scale of method development work
 - Not all clients are capable of evaluating newly developed methods
 - Not all methods come with clear documentation requirements
 - Not all methods come with a checklist
- Does TNI fit into this picture? And if so, how?

Three Areas of Policy Decisions

- Determining adequacy of the SOP
- Approach to laboratory assessments
- Development of proficiency testing samples

Determining the Adequacy of an SOP

- Who makes the decision about whether an SOP is adequate enough to develop accreditation standards?
- Our answer: we do
 - Our technical advisory body is helping us define a procedure
- But we think there is opportunity here for collaboration

Laboratory Assessments

- Who will develop the assessment checklist for novel methods?
- How are assessors trained?
 - New state agency needs often come without accompanying funding
- Our answer: we do, but again...
 - We would like help

Proficiency Testing Samples

- Who decides how complex the samples should be?
- Who decides the acceptable range of results?
- Whose job is it to work with providers to ensure PT samples exist?

How Does TNI Fit?



Contribute to the procedure for evaluating adequacy of new method SOPs



Review or test-drive draft assessment checklists



Share your experience



Other ways?

Thank you!

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