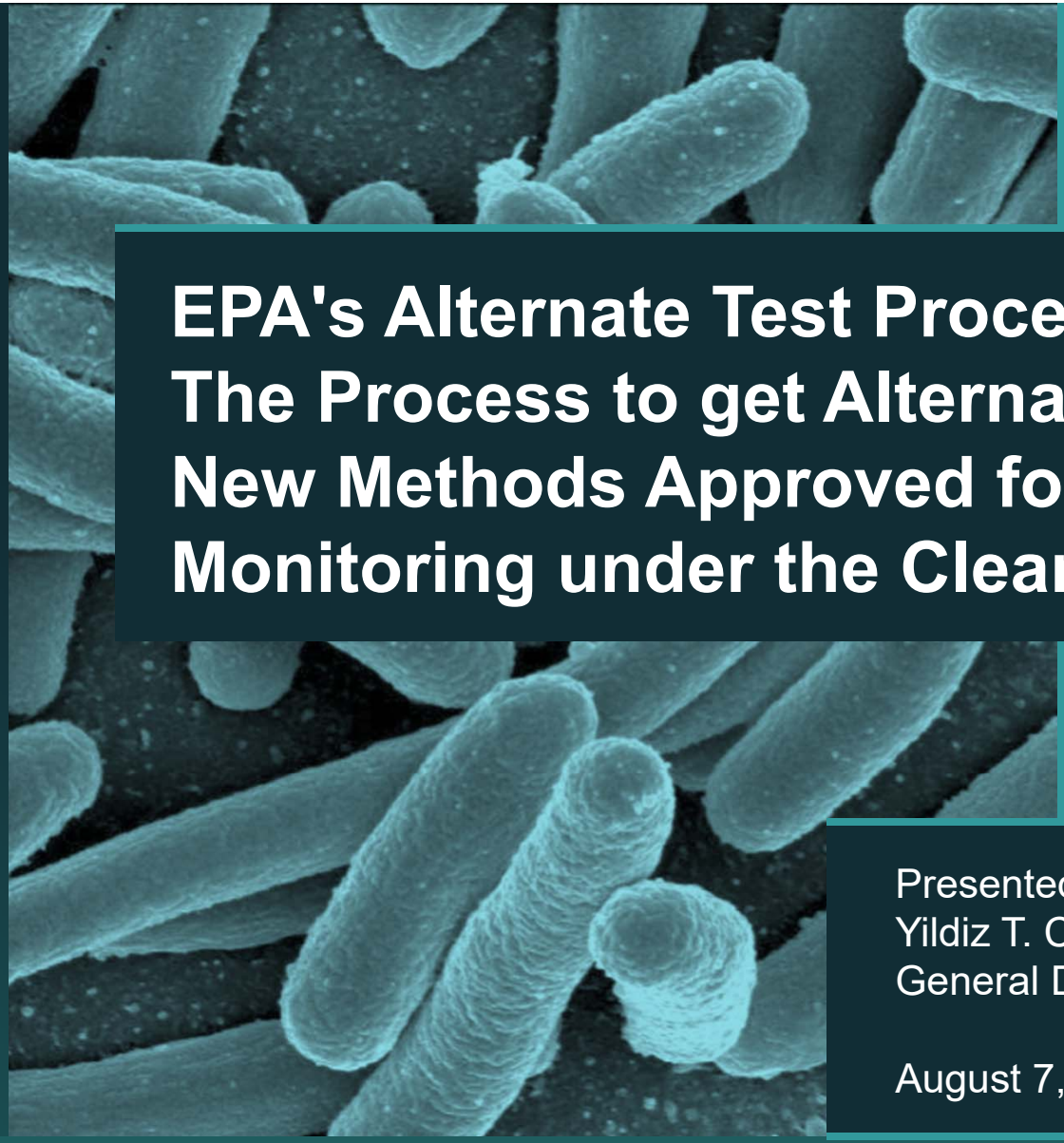
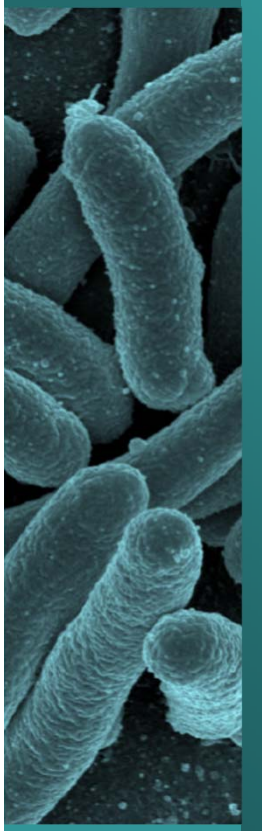


EPA's Alternate Test Procedure Program: The Process to get Alternate Methods or New Methods Approved for Compliance Monitoring under the Clean Water Act (CWA)

Presented by
Yildiz T. Chambers-Velarde, MSPH
General Dynamics Information Technology

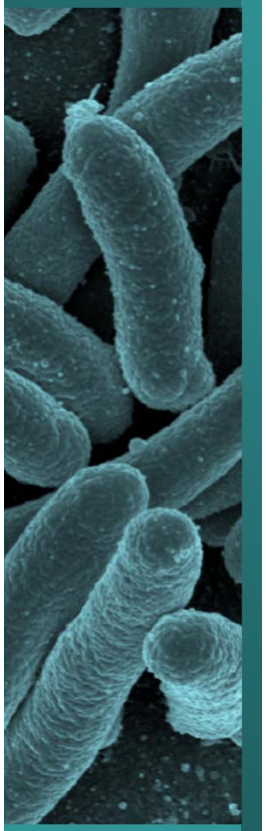
August 7, 2019

Co-authors



Lemuel Walker, Environmental Chemist
U.S. Environmental Protection Agency

Rashmi Ghei, Environmental Scientist
General Dynamics Information Technology



Disclaimer

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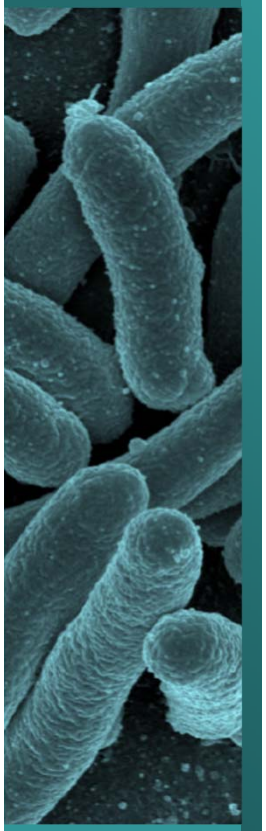
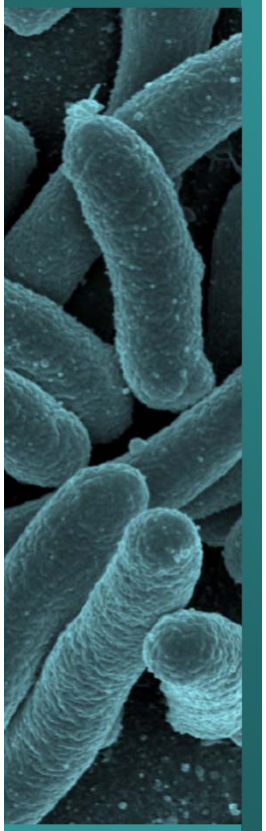
Background



- In accordance with the section 304(h) of the Clean Water Act (CWA), the U.S. EPA promulgates guidelines establishing test procedures (analytical methods) for the analysis of pollutants.
- EPA's regulations at 40 CFR Parts 136.4 and 136.5, allow entities to apply for Agency permission to use an Alternate Test Procedure (ATP) in place of an EPA-approved method and also establishes procedures for EPA to review and approve the use of an ATP.

ATP or New Method



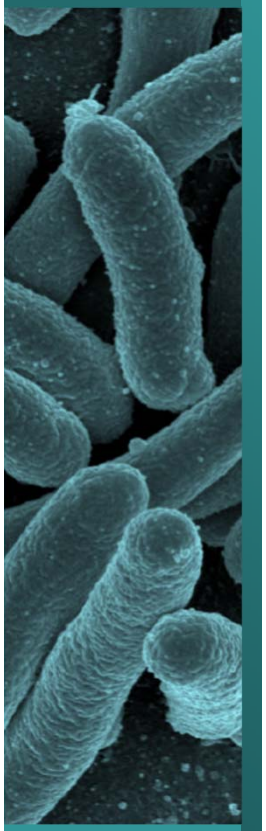
ATP

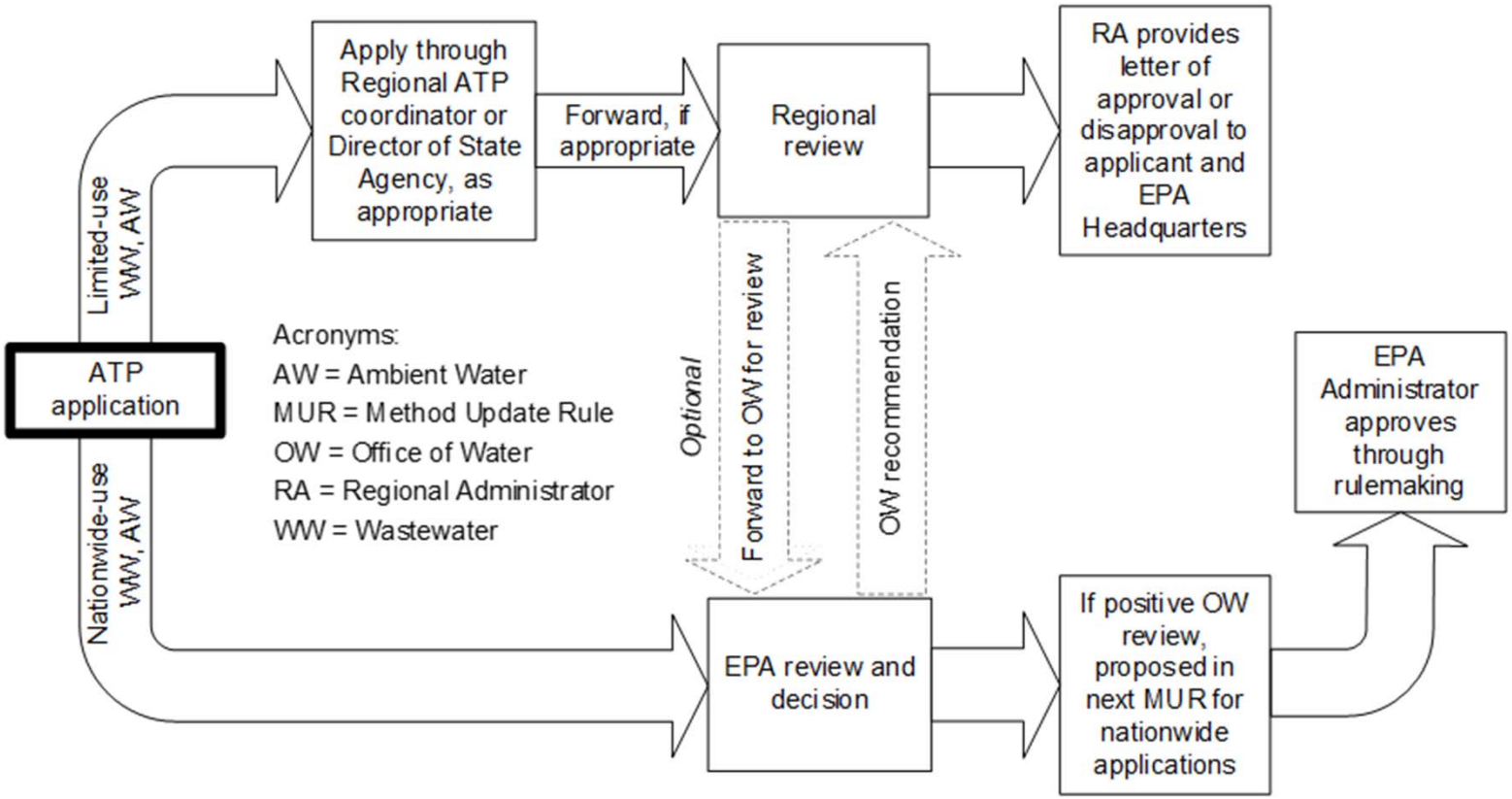
- Modification of an approved method or a procedure that uses the same determinative technique and measures the same analyte(s) of interest as the approved method

New Method

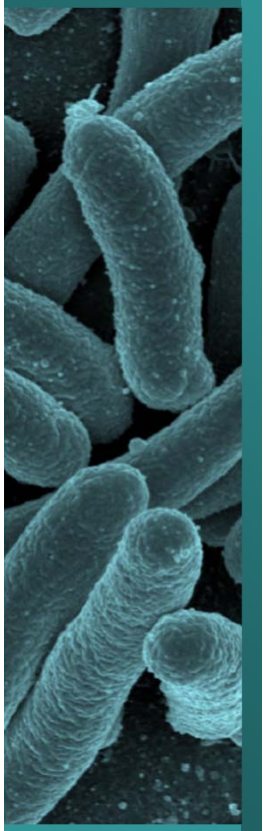
- The use of a different determinative technique to measure the same analyte(s) of interest as the approved method

Summary of the Review Process





ATP Applications



Types of Applications

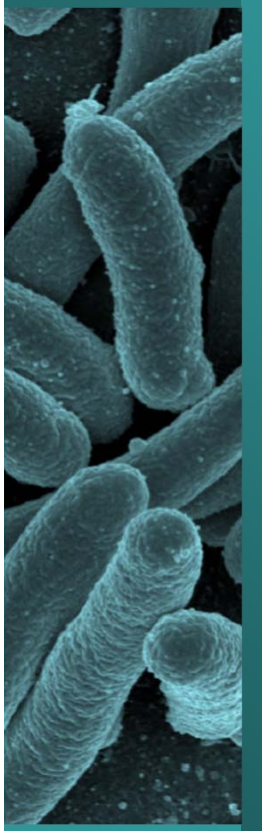
Limited Use

- Single laboratory
- One or more matrices
- Regional ATP Coordinator approves

Nationwide Use

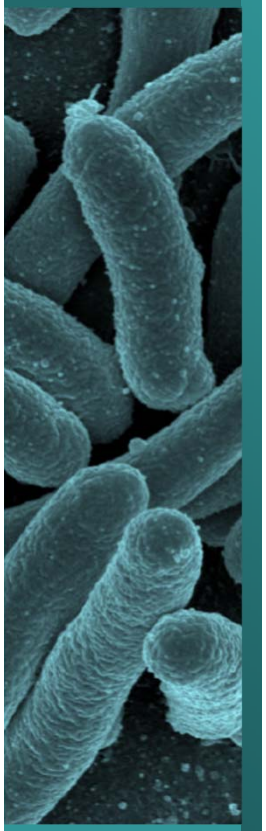
- All laboratories
- One or more matrices
- National ATP staff recommend for approval
- Promulgated through rulemaking

ATP Application Elements



- Completed application form
- Justification for the ATP
- Method in EPA format
- Study Plan
- Method comparison table
- Study report
- Method information and documentation

ATP Studies



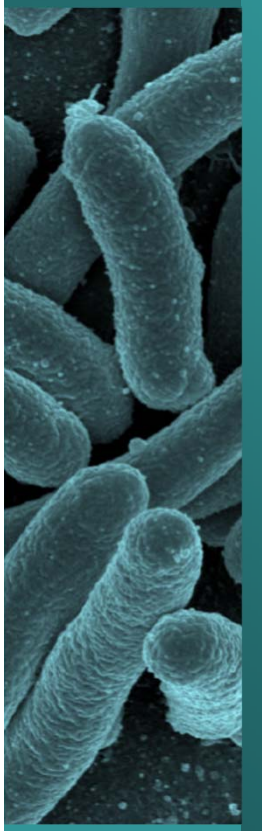
Types of Studies

Side-by-Side Comparison

- Parallel testing of the ATP and the reference method

QC Acceptance Criteria-Based

- Testing performance of the ATP based on the QC criteria associated with the reference method



Side-by-Side Comparison Studies

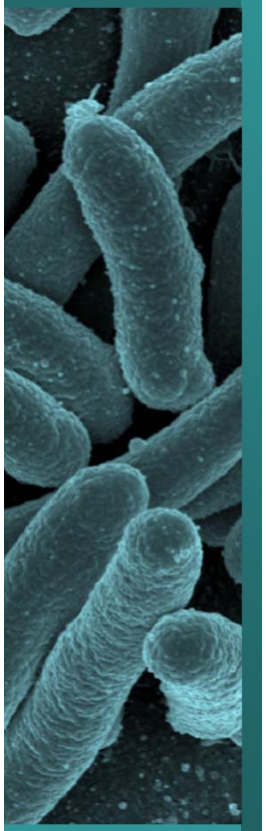
Limited Use

- Single laboratory
- One sample
- Five replicates

Nationwide Use

- Single laboratory
- Ten samples from geographically diverse locations
- Twenty replicates

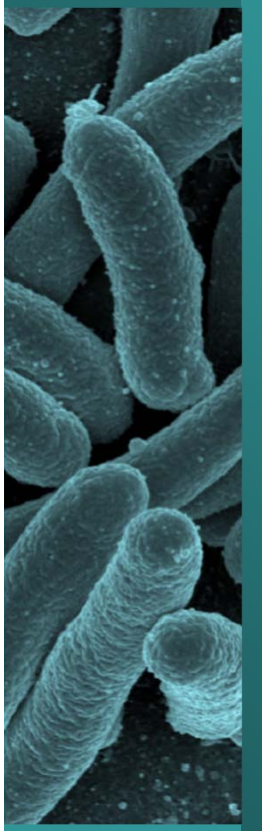
Side-by-Side Comparison Studies



Methods are compared using the following parameters:

- Recovery
- Precision
- False positive rate
- False negative rate

QC Criteria-Based Comparison Studies

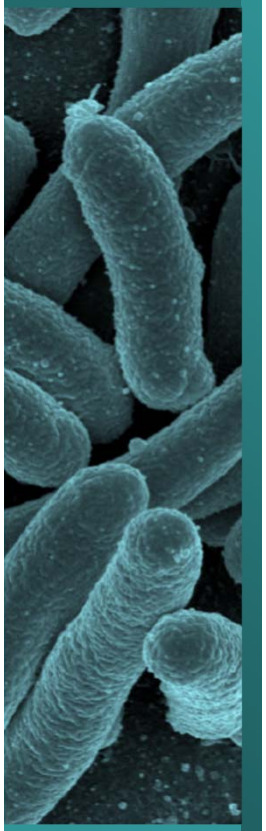


Limited Use

- Single laboratory
- Replicates
  - reference matrix – 5
  - matrix of interest – 3

Nationwide Use

- Ten laboratories
- Ten samples
- Replicates
  - reference matrix – 5
  - matrix of interest – 3



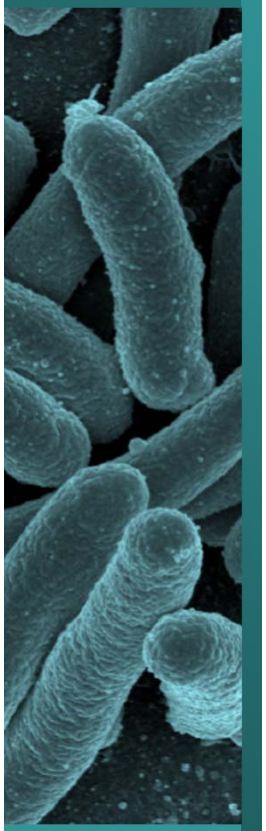
QC Criteria-Based Comparison Studies

Conducted to demonstrate that the ATP is able to meet the QC acceptance criteria for the reference method

- Very few microbiological methods have QC acceptance criteria
- QC criteria may not be sufficient to demonstrate comparability

QC Analyses

QC Analyses



Side-by-Side Comparison

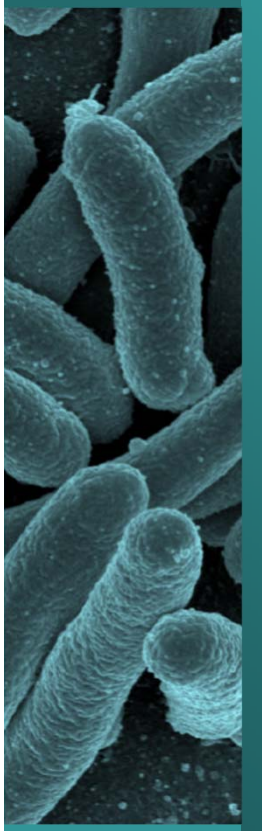
- Method Blank
- Positive Control
- Media Sterility Checks

QC Acceptance Criteria-Based

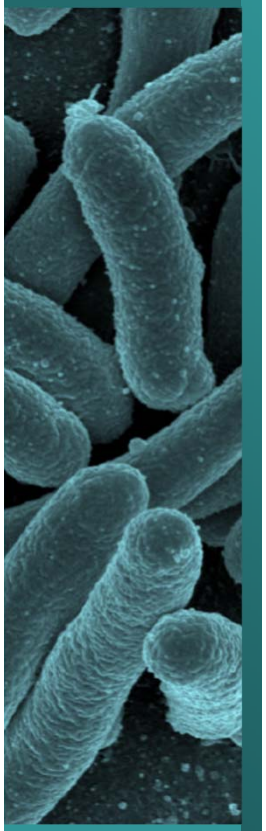
- Method Blank
- Media Sterility Checks

Data Analyses

Descriptive Statistics



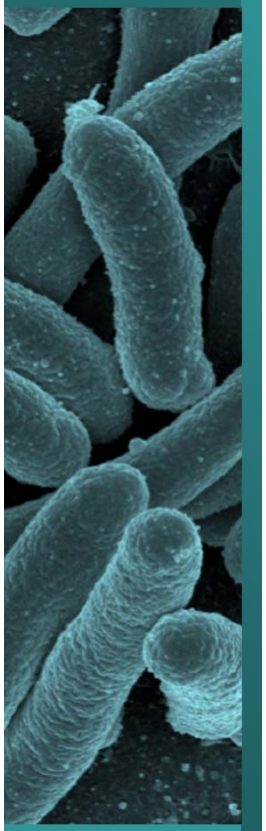
- Mean Recovery
  - For each matrix
- Precision
  - Standard deviation
  - Relative standard deviation
  - Relative Percent difference
- False Positive/False Negative Rates



Statistical Assessment of Method Comparability

Side-by-side Comparison

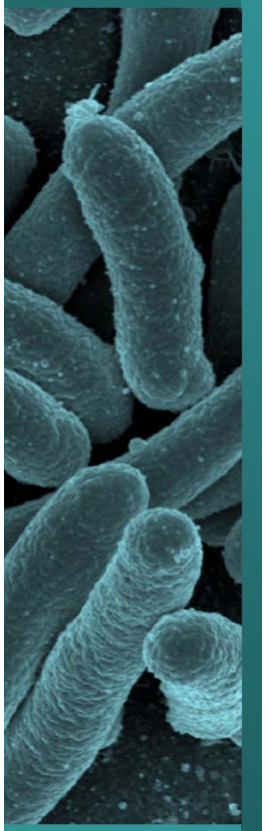
- Test for Normality
- Evaluation of Recovery and Precision
- False Positive/False Negative Rates
  - Assess matrix/method interactions
  - Assess method differences



Method Comparability Conclusions

- **Acceptable performance** – The ATP was similar or better than the reference method in at least 80% of the matrices used in the study
- **Unacceptable performance** – The ATP was only similar or better than the reference method in <80% of matrices

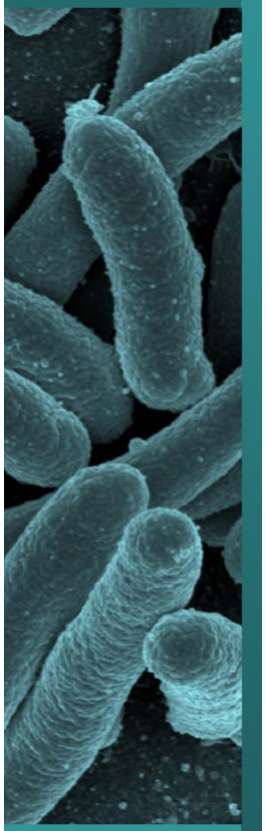
EPA Review and Approval



EPA Review

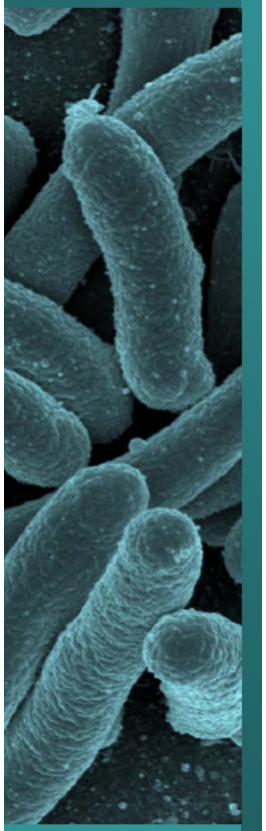
- Assessment of Compliance with Approved Study Plan
  - Study report and data
- Data Review
  - Raw data
- Data Validation
  - Supporting data (e.g., QC analyses, statistical analyses)

Approval Recommendation

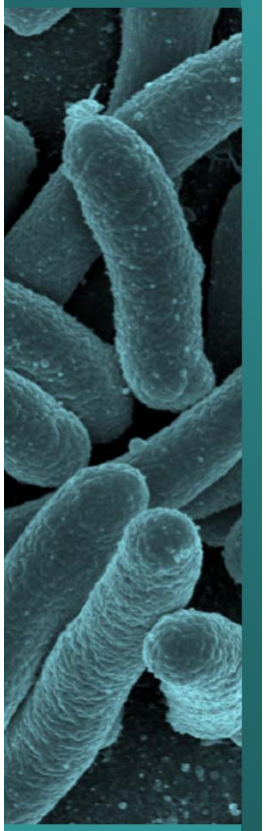


- Limited Use – ATPs will be approved by the EPA Regional ATP Coordinator
- Nationwide Use – ATPs will be approved through rulemaking

Rulemaking Process



- Method Update Rules (MUR)
  - 40 CFR Part 136
- Proposed Rule
  - Comment Period
- Final Rule
  - Publication
  - Effective Date



Key Points

- ATP studies should not be conducted without EPA approval of the study plan
- Deviations from the study plan require EPA approval
- To expedite approval, the applicant should submit a complete application and respond to EPA in a timely manner
- A minimum of 15 months between the publication of the proposed rule and the final rule in the *Federal Register*