# USDA-FSIS Public Meeting
# Control of *E. coli* O157:H7

## *Laboratory Perspective on Testing Methodologies*

**Wendy Warren-Serna, Ph.D.**

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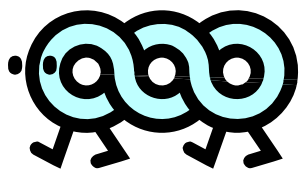
# It’s All in the Approach!

- Integrated use of:
  - *An effective sampling plan compliant with industry standards*
  - *Proper sample preparation and handling techniques*
  - *Validated and accurately applied test methods*
  - *Informed interpretation and application of test data*



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# Analytical Sample

- ***Analysis of the N60 sample***
  - *Assessment in the laboratory*
    - *Physical status*
      - *Temperature*
      - *Composition – merit in surface association*
    - *Piece count and weight compliance*
      - *Analysis of all 60 pieces for lot acceptance or rejection (e.g., 375-gram sample)*

# Test Method Considerations

- *"Equivalent to" or "As sensitive as" the USDA-FSIS method*
  - *USDA-FSIS Microbiology Laboratory Guidebook (MLG), Chapters 5.04 and 5A.01 (Effective 1/28/08)*

***How do you select such a method and/or determine if your current method meets this requirement?***

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# Method Selection

- Many drivers for method selection
  - Options are good for the industry
- Comparison of available test methods requires reliance on:
  - Validation data:
    - Definition of performance criteria and validation study design
    - Validation reports are ideally authored by a third party relative to the test kit manufacturer and available in the complete and original version
  - Basic principles of the scientific code of ethics surrounding method design and application
    - Transparency (sensitive to proprietary information) and replicable
    - ***Proper balance of science and economics***

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- Processor level
- &
- Laboratory level

***Challenges of balancing business and science***

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# Method Evaluation and Validation

- *Evolution of method validation for E. coli O157:H7 testing in beef.*
  - *AOAC-OMA to AOAC-RI to custom*
  - *AOAC-RI vs. Processor-specific method requirements*
- *In the absence of oversight and requirements, method validation varies and so do methods….*

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# Method Consistency

- *Inconsistent methods can lead to inconsistent results and expectations.*
- *Method consistency is driven by the establishment of performance criteria, proper validation and verification of consistent compliance with a method.*
- *Scientific consensus on the key elements of method performance for E. coli O157:H7 detection in beef is important to properly define performance criteria and direct method validation.*

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# The Think Tank Approach

- *Task force / committee approach can be a good way to outline method performance criteria*
  - *Drawback = timelines are generally long*
  - *Who pays for it?*
- *Beef Industry Food Safety Council (BIFSCO)-hosted STEC Methodology Think Tank*
  - *Multidisciplinary team with key stakeholders*
  - *Outline important elements of method validation relative to industry needs and in the interest of science*

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# The Think Tank Approach

- STEC methodology key validation elements were outlined (…interesting similarity to current *E. coli* O157:H7 method inconsistencies!):
  - Product to enrichment ratio
  - Type of product to be used (ground beef, trim)
  - The analytical unit (weight) of sample
  - Pre-warming of media, product temperature, and enrichment temperature
  - Type of enrichment media
  - Effect of initial inoculum dose on sensitivity**

**sensitivity in terms of probability of detection

**SOURCE: http://www.bifsco.org/uDocs/stecmethodolgythinktankforweb.pdf**

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# Testing Considerations

- ***Recovery of E. coli O157:H7 from beef requires careful compliance with validated methods.***
  - *Equal importance of sampling, sample prep, enrichment, post-enrichment handling (as applicable), and detection*
    - *Sample prep and enrichment activities must yield the proper number cells for delivery into the detection system*
    - *Activities must be prioritized to optimize the probability of detection*

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# Testing Considerations

- *Enrichment*
  - *Provide the best opportunity for growth*
    - *Basic needs – nutrient, time, temperature*
      - *Selectivity and efficiency*
    - *Product impact – composition, competing bacteria*
    - *Environmental impact – intervention, product handling conditions*
- *Post-enrichment handling*
  - *Should not reduce your probability of detection – validation within a specific detection system is a must (e.g., wet compositing or pooling).*
  - *Storage of the enrichment during the detection phase of testing is critical, especially if it may be subjected to further testing. Results can vary considerably, especially if the organism is near the limit of detection of the assay.*

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# Testing Considerations

- Detection
  - **Complete** understanding of the detection target(s), even if proprietary, needs to be understood (e.g., multiple genes from a general enrichment, individual protein, individual protein and individual gene, etc) so that pros/cons of a specific detection system can be clearly defined and an informed decision made.
  - Knowledge of the threshold level of cells required for delivery to the detection system for a **consistent positive result if the organism is present** is key so that probability of detection can be properly calculated, in particular if post-enrichment handling occurs and further testing is possible.

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# Laboratory Considerations

- ISO-17025 supports a good quality system
  - A thorough technical audit is a bonus at this point….not routine
- Quality and depth of laboratory staff to “self-police” technical aspects of the laboratory
- Ethical structure and influence of management
- A laboratory should welcome:
  - Auditing, transparency, peer review of methods employed at the laboratory
- Conflicts of interest should be clearly communicated so that third-party guidance can be employed as needed to ensure a proper balance of science and economics

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# Concluding Thoughts

- Test method consistency can be achieved by establishing expected performance criteria, including the probability of detection of *E. coli* O157:H7 at a specified level in the test sample, such that methods can be validated for compliance and in the context of a reference method.
- In the absence of an method validation body and established, industry-accepted performance criteria, test methods will continue to be inconsistent.
- In the absence of “technical policing” of laboratories, test methods may be improperly performed and/or applied.

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