Why Quantification? The Road to Revolutionizing Food Safety

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Organizer: Applied Laboratory Methods PDG

Moderator: Julia Poroshkova, Hygiena, United States

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Julia Poroshkova is the Marketing Specialist for Hygiena™ and resides in Chicago, IL. Julia has worked in Food Safety Industry for the past 4 years. Her previous experience includes a Marketing role at Merieux NutriSciences. She joined Hygiena last year and now leads the marketing communications for Molecular Diagnostics. Her favorite food industry tradeshow is the IAFP annual conference.
Dr. Mindy Brashears is the former Under Secretary of Agriculture in Food Safety where she served the USDA as a political appointee from 2019-2021. She is currently the Associate Vice President of Research at Texas Tech University and a Professor of Food Safety and Public Health holding the Roth and Letch family Endowed Chair of Food Safety. She also serves as the Director of the International Center for Food Industry Excellence at Texas Tech University. She holds a B.S. in food technology from Texas Tech (magna cum laude) and M.S. and Ph.D. degrees in food science from Oklahoma State University. Her research focuses on mitigation strategies in pre- and post-harvest environments and on the emergence of antimicrobial drug resistance in agricultural ecosystems. She has received multiple awards including the IAFP Laboratorian Award, The AMSA Research and Industry/Extension Award and was named as a Future Icon in the Meat Industry by the National Provisioner Magazine.
April Englishbey is the Product Manager for Hygiena™ Molecular Diagnostics and resides in Houston, TX. April’s industry experience began during her time at Texas Tech University while gaining her PhD in molecular and applied food microbiology. Creating ease-of-use and efficiencies while working with various levels of expertise throughout her career has been a driving force for April in her current role as Product Manager. Some of the most exciting recently launched product solutions that she has been a part of with the Molecular Diagnostics team are the BAX® System Real-Time *E. coli* O157:H7 Exact, BAX® Prep Xpress Automation, and SalQuant™. April’s favorite part of working for Hygiena is joining a team of innovative thinkers that were the pioneers of PCR and are continuing to develop solutions that truly improve food safety and consumer health.
Why Quantification?
The Road to Revolutionizing Food Safety

Presented By:
Dr. Mindy Brashears
Dr. April Englishbey
THE IMPORTANCE OF *SALMONELLA* QUANTIFICATION

Mindy Brashears, PhD
Associate Vice President for Research
Director-International Center for Food Industry Excellence
Roth and Letch Family Endowed Chair in Food Safety
Texas Tech University
Salmonella QUANTIFICATION NEEDS

- PERFORMANCE STANDARDS
- PROCESS CONTROL
- RESEARCH NEEDS
PERFORMANCE STANDARDS

1997
- Carcass Sampling
- Traditional Methods of Detection
  - Almost always pass

Modernized Performance Standards
- Targeted Sampling
- New Baselines Targeting High Risk
  - Detection Only
PERFORMANCE STANDARDS FSIS

- Salmonella in Poultry
- Proposed Campylobacter in Poultry
- Proposed Salmonella in Beef
- Upcoming Salmonella in Pork
ESTABLISHING PERFORMANCE STANDARDS

- Salmonella Baselines of Percent Positive
- Human Illness Data
- HP2030 Reduction (30%)
- Reduction of the Percentage Positive to achieve HP2030 Goals
HOW DO WE SET PERFORMANCE STANDARDS?
Example: Ground beef – *Salmonella*

Source: FSIS
HAVE PERFORMANCE STANDARDS BEEN EFFECTIVE?

Chicken Parts Prevalence 12-month Moving Average or % in Cat. 3

Salmonella Prevalence or % in Cat. 3

1st FRN

2nd FRN

Public Posting

Source: FSIS
STAKEHOLDERS STATE THAT PERFORMANCE STANDARDS AREN’T WORKING??

• *Salmonella* in Poultry

• Declines began in 2018

• Attribution data in 2018 and 2019 (Don’t have more recent) do not indicate reductions in human illness

• *E. coli* O157:H7 Adulterant in 1994

Too soon to tell....
CHALLENGES

Lack of Rapid Quantification Data

Slow Reporting of Attribution Data by CDC
THE FUTURE

QUANTIFICATION AND RISK CONSIDERATION

AOAC Approved Rapid Quantification Methods Make Quantification Possible

Industry and Academia have Already Adopted these Methods
PERFORMANCE STANDARDS SHOULD BE BASED ON QUANTIFICATION for Salmonella
4 of 18 Positive for *Salmonella* = 22.2%

But only 1 > 4 logs (> 10,000) CFU/mL
PROBABILITY OF ILLNESS VS. LOG DOSE

1 Log = 10 ufc/ g
2 Log = 100 ufc/ g
3 Log = 1,000 ufc/ g
4 Log = 10,000 ufc/ g
5 Log = 100,000 ufc/ g
6 Log = 1’000,000 ufc/ g
7 Log = 10’000,000 ufc/ g

……….

- Y-axis: Probability of Illness
- X-axis: Log Dose

Graph showing the probability of illness increasing with the log dose.
Salmonella COUNTS VS PREVALENCE

Data collected using BAX® System Q7 and SalQuant™
Salmonella RISK IS NOT THE SAME AS STEC
Majority of Isolates are in Kentucky

Many Fall below Quantification
CHALLENGES OF RULEMAKING

Government Process
- NOT THE FAULT OF THE AGENCY

Proposed Rule/Public Comment/Final Rule

Technology has already Leap-Frogged the Agency Approach
RESEARCH NEEDS

Quantitative Biomapping *Salmonella* in Process

Identification of Pathogenicity Genes

Method Development for Rapid Detection of Pathogenicity Genes

In-Plant and Laboratory Rapid Quantification
Addressing the Challenges of the Future

April Englishbey, PhD
Global Product Manager – Molecular Diagnostics
Hygiena

Quantification And Risk Consideration

AOAC Approved Rapid Quantification Methods Make Quantification Possible

Quantitative Bio-mapping *Salmonella* in Process
Addressing the Challenges of the Future

- Quantification and Risk Consideration
  - Enumerable Range
  - Lower Limit of Quantification (LOQ)

- What we have observed through Hygiena™ SalQuant™ applications:

  - **Live Production (On-Farm)**
    - 0.0 – 4.0 Log CFU/mL(g)
    - (1 – 10,000 CFU/mL(g))

  - **Processing (Rehang – Pre-Chill)**
    - 0.0 – 3.0 Log CFU/mL
    - (1 – 1,000 CFU/mL)

  - **Final Product (Post-Chill, Parts, Ground)**
    - 0.0 – 1.0 Log CFU/mL(g)
    - (1 – 10 CFU/mL(g))
Addressing the Challenges of the Future

Quantification and Risk Consideration

- Sample Flexibility
- We are all still learning as an industry what sample type correlates best to risk throughout the poultry production chain!
- With industry partners, over 14 matrices have been identified as potential tools:

  - Primary Production
    - Boot Swabs
    - Dust Swabs
    - Feet Swabs
    - Cloacal Swabs
    - Poult Pads
    - Feed
    - Ceca tonsils
    - Crops
    - Lungs

  - Processing
    - Carcasses
    - Parts

  - Final Product
    - Ground Chicken
    - Ground Turkey

  - Environmental
    - Swabs

Request SalQuant™ methods at www.hygiена.com/salquant-poultry
Addressing the Challenges of the Future

AOAC Approved Methods

• 3 Levels of Quantification (Low, Medium, High, Negative)
  • 5 samples per level + 5 Negative Controls

• Equivalency between reference (MLG MPN) vs candidate (+/- 0.5 Log CFU)

• Does enumerable range meet industry need?

Data collected using BAX® System Q7 and SalQuant™
Addressing the Challenges of the Future

Quantitative Bio-Mapping in Process: Flock to Final Product

Information Needed:
- Incoming Load
- Intervention Efficacy
- Consumer Risk

Sample Type:
- Boot Swabs
  - Rehang
  - Pre-Chill
  - Post Chill
  - Whole Carcass
  - Parts

Actions:
- None
  1. Initial Processing Load
  2. Correlation back to farms BUT no actions applied at pre-harvest
- None
Addressing the Challenges of the Future

Quantitative Bio-Mapping in Process: Flock to Final Product

Information Needed:
- **Incoming Load**: Numerical values for always positive results
- **Intervention Efficacy**: Reduction at each intervention
- **Consumer Risk**: Salmonella levels in final product

Sample Type:
- **Boot Swabs**
- **Rehang**
  - Pre-Chill
  - Post Chill
- **Whole Carcass**
- **Parts**

Actions:
1. Influence slaughter order
2. Treatments to lower load
3. Investigate farms for hygienic improvements
1. Continuous control tracking
2. Evaluation of interventions for cost savings and meeting specifications
3. Traceability of final product to source/flock
1. Consumer risk
2. Traceback investigation support
3. Aid in performance standards
4. Diversion decisions
Addressing the Challenges of the Future

Quantitative Bio-Mapping in Process: Troubleshooting and Traceback

- Large chicken producer in US
- Currently sampling:
  - Final Product Parts

“We’ve been seeing some Salmonella positives on parts recently, with a prevalence of 7% on tenders and 15% on breasts.

**Using only the prevalence data, we would have been inclined to focus on the breasts.**

But **after running Quantification**, we actually see a much higher quantification on tenders than breasts, so we’ve **refocused our energy on investigating** the tenders’ process.

This is just a quick example of how **the technology has allowed us to better optimize our resources**. We’re very vocal advocates of the system to our connections in the industry!”

Data collected using BAX® System Q7 and SalQuant™
Why Quantification?

The Road to Revolutionizing Food Safety

THANK YOU!

QUESTIONS?
Contact Information

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- Mindy Brashears  mindy.brashears@ttu.edu
- April Englishbey  aenglishbey@hygiiena.com
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January 26, 2022  Practical Guidance for Validation Studies: From Start to Finish

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