USDA
United States Department of Agriculture

FOOD SAFETY AND INSPECTION SERVICE

*Salmonella: State of the Science*

Tuesday, September 22, 2020
9:00 am – 5:00 pm ET
Logistics

Shayla Bailey
Moderator, FSIS, USDA
9:00 AM Logistics
Shayla Bailey, Moderator, FSIS, USDA

9:05 AM Welcome
Paul Kiecker, Administrator, FSIS, USDA

9:10 AM Opening Remarks
Mindy Brashears, PhD, Under Secretary for Food Safety, USDA

9:30 AM Bending the Foodborne Illness Curve
Frank Yiannas, MPH, Deputy Commissioner for Food Policy and Response, FDA

10:00 AM Public Health Challenge of Salmonellosis in the 21st Century
Robert Tauxe, MD, MPH, Director, Division of Foodborne, Waterborne, and Environmental Diseases, CDC

10:30 AM Salmonella Trends – What the Science Tells Us
Kis Robertson Hale, DVM, MPH, Chief Public Health Veterinarian and Deputy Assistant Administrator, Office of Public Health Science, FSIS, USDA
10:45 AM BREAK

11:00 AM Scientific Basis for Performance Standards
Denise Eblen, PhD, Assistant Administrator, Office of Public Health Science, FSIS, USDA

11:15 AM How FSIS Laboratories Support Efforts to Reduce Salmonella
William Shaw, PhD, Executive Associate for Laboratory Services, Office of Public Health Science, FSIS, USDA

11:30 AM Role of Science in Modernizing Inspection Systems
Philip Bronstein, PhD, Assistant Administrator, Office of Field Operations, FSIS, USDA

11:45 AM LUNCH
12:15 PM Welcome Back and Housekeeping
Shayla Bailey, *Moderator*, FSIS, USDA

12:20 PM Role of Science in Consumer Research and Education
Carol Blake, *Assistant Administrator*, Office of Public Affairs and Consumer Education, FSIS, USDA

12:35 PM Roundtable Discussion
Shayla Bailey, *Moderator*, FSIS, USDA

1:05 PM Role of Research at FSIS
Isabel Walls, *PhD*, Senior Public Health Advisor and Scientific Liaison, Office of Public Health Science, FSIS, USDA

1:15 PM USDA Agricultural Research Service Research to Reduce *Salmonella* Contamination in FSIS-regulated Products
Kimberly Cook, *PhD*, and James Lindsay, *PhD*, National Program Leaders, Food Safety, ARS, USDA
1:45 PM BREAK

2:00 PM Future Challenges and Opportunities
Mindy Brashears, PhD, Under Secretary for Food Safety, USDA

2:15 PM Pre-registered Public Comment
Shayla Bailey, Moderator, FSIS, USDA

4:45 PM Closing Remarks
Terri Nintemann, Deputy Administrator, FSIS, USDA

5:00 PM Adjourn
Welcome

Paul Kiecker, Administrator, FSIS, USDA
Salmonella: State of the Science

Mindy Brashears, Ph.D.
Under Secretary for Food Safety
U.S. Department of Agriculture
FOOD SAFETY AND INSPECTION SERVICE

Salmonella: State of the Science
Lead With Science

Influence Behavior Changes

Build Relationships

FSIS
Federal Meat Inspection Act (FMIA)

Poultry Products Inspection Act (PPIA)

Egg Products Inspection Act (EPIA)
The Interagency Food Safety Analytics Collaboration (IFSAC) estimates that approximately 38% of foodborne salmonellosis in the United States is attributed to meat and poultry products.
Salmonella Infections Commonly Transmitted Through Food

Per 100,000 population

Total Cases
Healthy People 2020 Goal

1997 1999 2001 2003 2005 2007 2009 2011 2013 2015 2017
Roadmap to Reducing Salmonella
Driving Change through Science-Based Policy
Modernization of Inspection Systems
FSIS Laboratories and Sampling
Salmonella Performance Standards
Outreach and Communication
Data Transparency and Analytics
Research Innovation
Collaboration with Public Health Partners
FOOD SAFETY AND INSPECTION SERVICE
Do Right and Feed Everyone…Safely!
Bending the Curve of Foodborne Illness

Frank Yiannas
Deputy FDA Commissioner
Office of Food Policy and Response

@FrankYiannasFDA
Est. percentage of foodborne illnesses attributed to food categories, based on multiyear outbreak data (1998-2017)

Recalled for *Salmonella* Risk: Peaches, Onions
Searching for Pathogens in Produce Sampling
Science
Outbreaks in Low-Moisture Foods


2008, 2018


2010

2013, 2018, 2019
FOOD SAFETY MODERNIZATION ACT
Agricultural Water Quality, Testing and Treatment
Ensuring Parity in Regulatory Oversight

- FSMA established the Foreign Supplier Verification Programs rule, which requires importers to verify that food imported into the U.S. has been produced in a manner that meets applicable U.S. safety standards.
Proposed Rule: Food Traceability Rule
NEW ERA OF SMARTER FOOD SAFETY
FDA’s Blueprint for the Future
Welcome to FDA's New Era of Smarter Food Safety

Tech-enabled Traceability

Smarter Tools and Approaches for Prevention and Outbreak Response

New Business Models and Retail Modernization

Food Safety Culture
Advancing Traceability

• FDA’s Food Traceability Rule is a first step

• Will harmonize the information and data needed for enhanced traceability

• Lays foundation for end-to-end traceability
Using AI to Prevent Violative Imported Foods from Entering Commerce

Number of imported food shipments by exporting country/region

- Mexico
- Asia
- Canada
- Europe
- All Others
Calls to Action to Stop Recurring Outbreaks tied to Imported Papaya
“Alone, we can do so little; Together, we can do so much.”
Public Health Challenge of Salmonellosis in the 21st Century

Road Map to Reducing Salmonella: Driving Change through Science-Based Policy

Salmonella – State of the Science at FSIS
Food Safety and Inspection Service, USDA
September 22, 2020

Robert Tauxe, MD, MPH, Director
Division of Foodborne, Waterborne, and Environmental Diseases, NCEZID, CDC
Salmonellosis in the United States

- Domestically-acquired foodborne salmonellosis: Every year an estimated 1 million become sick, 19,000 are hospitalized, and 380 die.
- Little progress has been made in reducing incidence in last 20 years.
- Prevention: Understanding transmission well enough to prevent it.
- Result of actions by regulators, public health, industry, consumers.
- Whole genome sequencing provides better tools for surveillance, investigation and source attribution.
- Can help drive progress with better scientific understanding that leads to changes in industry practices and regulatory policies.
Salmonella is the major bacterial foodborne illness challenge in the United States

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Foodborne illnesses</th>
<th>Foodborne hospitalizations</th>
<th>Foodborne deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella</td>
<td>1,000,000</td>
<td>19,000</td>
<td>380</td>
</tr>
<tr>
<td>Campylobacter</td>
<td>845,000</td>
<td>8,500</td>
<td>80</td>
</tr>
<tr>
<td>E. coli O157</td>
<td>63,000</td>
<td>2,100</td>
<td>20</td>
</tr>
<tr>
<td>Listeria</td>
<td>1,600</td>
<td>1,500</td>
<td>260</td>
</tr>
</tbody>
</table>

Scallan, Emerg Infect Dis, Jan 2011. Estimated annual number of domestically acquired foodborne illnesses, hospitalizations, and deaths.
Outline of Food Safety Activities at CDC

- Conduct national surveillance for infections often transmitted by food
- Investigate and control outbreaks to stop them and prevent future illness, and investigate sources of sporadic infections
- Support state and local health departments, regulatory, and other partners to fulfill their primary roles in food safety
- Innovate by applying advanced technologies to improve surveillance and to address diagnostic challenges
- Drive illness prevention policy with scientific data, analyses, and partnerships
Many partners in surveillance, investigation and control

- Caregivers, clinical labs, and patients themselves
- State and local health departments: epi, lab, and food safety officials
- CDC: lead national public health agency
- Federal partners: FDA regulates most foods, FSIS meat and poultry
- Academic partners: targeted research, analysis, and training
- Industry, assisting with traceback, recalls, and prevention measures
- Consumers and their advocates
National surveillance for salmonellosis

- **Case reports:** Clinical labs send *Salmonella* to public health laboratories for serotyping
- **FoodNet:** Collaborative effort (CDC/FSIS/FDA)
  - 10 sites, 15% of the population
  - Active surveillance, systematic collection of outcome data
  - Population surveys for frequency of illness and exposures
- **PulseNet:** Typing *Salmonella* by genetic methods in public health labs to supplement serotyping (40,000/yr)
  - July 2019: switched to whole genome sequencing
  - October 2020: tools for rapid allele-based analyses, resistance prediction
  - Find more clusters that may be related, find them while smaller
  - New tool for source attribution of sporadic cases
- **NARMS:** 1 in 20 *Salmonella* serotyped sent to CDC for resistance determination
- **Reported outbreaks:** Reports of Investigations of single state & multistate outbreaks
  - about 150 foodborne outbreaks a year, 40 of them multistate
Trend in salmonellosis, United States, FoodNet, 1996-2019

Incidence of *Salmonella* Infections by Year

Incidence per 100,000 persons by year for FoodNet sites
1996-2019; all test methods
* Culture-confirmed includes those infections confirmed by culture only or by culture following a positive CIDT.
Source: FoodNet, Centers for Disease Control and Prevention

1996: 14.5/100,000
2019: 14.9/100,000 culture confirmed
17.1/100,000 with CIDTs

2030 Healthy People Goal: 11.1/100,000

FoodNet Fast, Aug 9, 2020
External factors impacting surveillance recently

- CIDTs (Since 2015):
  - More clinical laboratories use culture-independent diagnostic tests (CIDTS)
  - Test ordered more often than traditional culture was
  - Rapid diagnosis of “Salmonella infection”, but no serotype or antibiogram
  - Reflex culture of positive sample can yield strain (often by state health labs)
  - Future: Metagenomic assays that recover genome without culture

- COVID-19: 2020 Surveillance results will be different
  - Clinic visits, ER visits, specimen submissions to clinical labs decreased
  - Sequences submitted to PulseNet down by 50% in April, now down 25%
  - State resources focused on response to COVID-19
  - Fewer clusters found, fewer outbreaks solved
### Incidence of *Salmonella* infections – Top 5 serotypes

<table>
<thead>
<tr>
<th>Serotype</th>
<th>Incidence lab-confirmed (per 100,000) per year</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enteritidis</strong></td>
<td>3.0</td>
<td>20</td>
</tr>
<tr>
<td>Newport</td>
<td>1.7</td>
<td>11</td>
</tr>
<tr>
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<td>1.6</td>
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<tr>
<td>Javiana</td>
<td>1.3</td>
<td>8</td>
</tr>
<tr>
<td>4,[5],12:i:-</td>
<td>1.0</td>
<td>7</td>
</tr>
<tr>
<td><strong>Top 5</strong></td>
<td>-</td>
<td>56</td>
</tr>
<tr>
<td><strong>All</strong></td>
<td>15.4</td>
<td>100</td>
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*FoodNet, 2015-2017*
Among the top 5 serotypes, four are increasing and Typhimurium is decreasing.
Why would Typhimurium be decreasing? Is this a result of a prevention effort targeting Heidelberg?

- Heidelberg was the 4th most common serotype 15 years ago
- 2013-14: Large outbreak of Heidelberg infections linked to one West Coast poultry producer. Chicken parts from several farms contaminated
- Multi-hurdle control efforts by producer:
  - Requiring chicks from source flocks to be Heidelberg free
  - Vaccinating broiler breeder flocks (bactrins + live Typhimurium vaccine)
  - More interventions on chicken parts at processing (to under 5%)
- Similar interventions by other major producers, new parts rule by FSIS
- Typhimurium vaccine effective against Heidelberg and perhaps other antigenically related serotypes in same “Group B” serogroup (now O:4)
Two apparent successes in *Salmonella* prevention: 1996-2019

S. Heidelberg declines 93% to 0.08/100,000 in 2019

S. Typhimurium declines 72% to 1.27/100,000 in 2019

From FoodNet Fast: cdc.gov/foodnetfast
What are the sources of salmonellosis? Attribution using food vehicles determined in outbreaks - United States, 1998 - 2017

- Multi-agency collaborative effort (IFSAC)
- Outbreaks reported to national surveillance that implicate a food
- We divided all foods into 17 commodity groups
- We included outbreaks where the implicated food was a single food commodity
- 811 such salmonellosis outbreaks reported to CDC 1998-2017
- Discounted those reported more than 5 years earlier

IFSAC 2017 Report
https://www.cdc.gov/foodborneburden/attribution/partnerships.html

Meat and Poultry = 38.0%
Chicken = 14%
Pork = 10.3%
Beef = 6.4%
Turkey = 6.2%
Other meat/poultry = 0.1%

IFSAC 2017 Report
What are the sources of individual serotypes?

- Attribution using food vehicles found as sources in outbreaks
- Attribution by conducting case-control studies of sporadic cases
- Attribution by comparing collections of strains from human infections and those found in food or animal sources
  - Limited success with PFGE for common serotypes
  - Now approaching with whole genome sequence typing
  - Promising method, starting with *Salmonella* Enteritidis
  - Start by distinguishing strains from eggs sources vs chicken sources
- Can WGS help attribute sources of sporadic cases and predict source in outbreaks?
- This may guide prevention measures to reduce burden of illness
Incidence of *Salmonella* infections

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FoodNet, 2015-2017
In the early 2000s, there were many Enteritidis outbreaks due to eggs – now more are due to chicken.
New landscape of bacterial foodborne events revealed by surveillance using whole genome sequencing

- Finding more outbreaks, finding them while they are smaller
  - Identifying familiar and new sources of *Salmonella*
  - Kratom, pig ear dog treats, red onions

- Clarifying events that go beyond acute outbreaks: “REP strain” events
  - **Re-occurring** outbreaks caused by the same strain
  - **Emerging** strain that spreads within one animal species
  - **Persisting** strain that continues for years
  - Often multi-drug resistant

- Adding allele codes to make REP strains easier to track
- Plan to provide quarterly updates on them
- Focusing more effort on them can help target prevention strategies
## Incidence of *Salmonella* infections

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<td>Muenchen</td>
<td>0.4</td>
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*FoodNet, 2015-2017*
Incidence of Infantis infections began increasing in 2010, and then became MDR
REP Strain Example: Emerging event traced to a complex source: 
**MDR Salmonella Infantis and poultry**

- MDR strain first seen in travelers from Peru in 2012
- Resistant/Decreased susceptibility to 10 agents, including Amp, Cipro, Ceftriaxone, and Tmp/Sxt
- First non travel-associated US case in 2014
- Increased rapidly in 2017-2018
- Driving increase in Infantis (Now 6th most common)
- 2019: 30% of S Infantis in humans is MDR
- Can define as a WGS allele group

**Case map: Salmonella Infantis MDR strains 2012-2019**

(n = 1246)

- USDA/FSIS isolates: In chicken since 2013, rapid increase in 2017
- Many different slaughterhouses, brands, chicken products
- In 2018: 495 isolates from chicken, 53 isolates from turkey
- Met with National Chicken Council several times in 2018, 2019
- Preharvest investigations and interventions needed

Thanks to Louise Francois Watkins
Targeted prevention can work

- We can make progress with tools we have now.
- Successful control of Heidelberg, once 4th most common serotype, (perhaps as a result of Typhimurium vaccination in layers and broiler breeders)
- Enteritidis is the most common serotype (20%), largely from poultry and eggs
  - Enteritidis can be addressed in broiler flocks with approaches successful in egg-laying flocks, including Enteritidis bactrins and live Typhimurium vaccines
  - UK largely controlled it with vaccination of both kinds of flocks
Targeted prevention can work
Reported salmonellosis, United Kingdom: 1981 - 2010

Total Salmonella

Salmonella Enteritidis strain linked to eggs and chicken

O’Brien 2013 CID:56 705-10
Targeted prevention can work
Reported salmonellosis, United Kingdom: 1981 - 2010

Vaccination of broiler-breeders began

O'Brien 2013 CID:56 705-10
Targeted prevention can work
Reported salmonellosis, United Kingdom: 1981 - 2010

Key:
(a) S. Enteritidis phage typing began;
(b) CMO issued advice to vulnerable groups;
(c) Compulsory slaughter began;
(d) Compulsory slaughter revoked;
(e) Vaccination of broiler-breeder flocks began;
(f) Vaccination of laying flocks began;
(g) Lion Flock fully vaccinated.

O’Brien 2013 CID:56 705-10
Targeted prevention can work

- We can make progress with tools we have now.
- Heidelberg, once 4th most common serotype, is now disappearing (perhaps as a result of Typhimurium vaccination in layers and broiler breeders)
- Enteritidis is the most common serotype (20%), largely from poultry and eggs
  - UK largely controlled it with vaccination of both kinds of flocks
  - Enteritidis can be addressed in broiler breeder flocks with approaches successful in egg-laying flocks: including Enteritidis bactrins and Typhimurium live vaccines

- Chicken is the most common animal food source, accounting for 14% of cases
  - How can the proportion of chicken parts that yield *Salmonella* be further reduced?
  - Can more producers and retailers add specific purchase specifications?
- Now with WGS, we can define specific REP strain targets
  - Root cause investigations upstream from slaughterhouses
  - Collective commodity-specific prevention strategies
Targets for specific control measures

- MDR Infantis: Retail chicken
- MDR Newport: Beef
- MDR 4,[5],12:i:-: Pork
- MDR Reading: Turkey
- Enteritidis: Eggs and retail chicken
- Pork
- Reading Turkey
Coming soon: New estimates of health burden, trends in infections and attribution to specific food sources

- Foodnet: New estimates of progress by pathogen each spring
- Modeling to adjust for effect of CIDTs on reporting, to accurately track progress towards Healthy People 2030 goals
- Recent FoodNet population survey will help prepare new estimates of the burden of illnesses, hospitalizations and deaths
- Source attribution by food type improving:
  - Now done with outbreak data
  - Starting to use WGS to provide source attribution of sporadic cases

- Results of surveillance available online at
  - NARMS Now for antibiotic resistance data [www.cdc.gov/narmsnow](http://www.cdc.gov/narmsnow)
  - National Outbreak Reporting System NORS Dashboard [www.cdc.gov/norsdashboard](http://www.cdc.gov/norsdashboard)
Foodborne salmonellosis prevention in the 21st century

- Most frequent bacterial cause of foodborne illness in the US
- Incidence has not decreased in 20 years: New approaches to prevention needed
- Serotype Enteritidis = 20%
- Poultry = 20%
- Sources vary by serotype and strain
- More outbreaks of Enteritidis from chicken than from eggs
- Re-occurring, emerging and persistent strains are sometimes highly drug resistant and may have specific reservoirs
- WGS-based surveillance means:
  - More outbreaks and sources detected, defined, and controlled
  - More food safety gaps found and corrected
  - Systematic approach to REP strains as specific targets for prevention

Empower public health, regulators, industry, and consumers to drive down incidence of foodborne infections
Salmonellosis in the United States – Headline News
An IT challenge in many states: Internet upload speeds for PulseNet laboratories
REP Strain Example: Persisting event traced to a sustained source: *Listeria monocytogenes* and boiled eggs

- 7 infections with the same *Listeria monocytogenes* strain (by WGS) observed over 3 years in 5 states,
- Median age 75, 4 hospitalized, 1 died
- 4/5 ate foods containing eggs, 3 sure it was egg salad
- Same strain found in environmental samples collected during FDA inspection of large egg-boiling facility in Feb 2019, and again in December 2019

- **Public Warning and Recall**
  - *L mono* present in peeling room, apparently for many months, or years?
  - Bulk hard-boiled eggs used in many other RTE products
  - Public and commercial sector warned, production temporarily halted, all hard boiled eggs from that facility recalled, processes under review
  - **Underlines need for vigilant public health surveillance, and environmental monitoring and sanitation**
## Surveillance and investigation are multi-agency efforts

<table>
<thead>
<tr>
<th>Organization</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caregivers and clinical labs</td>
<td>• Make the diagnoses, and report the specific illnesses</td>
</tr>
<tr>
<td>State and local health</td>
<td>• Receive reports of specific diseases, and interview patients</td>
</tr>
<tr>
<td>departments</td>
<td>• Subtype pathogens in the public health labs to find dispersed outbreaks</td>
</tr>
<tr>
<td></td>
<td>• Investigate and control events within the state</td>
</tr>
<tr>
<td></td>
<td>• Ongoing monitoring and prevention activities</td>
</tr>
<tr>
<td>CDC</td>
<td>• Serves as the lead national public health agency</td>
</tr>
<tr>
<td></td>
<td>• National disease surveillance and multistate outbreak detection and</td>
</tr>
<tr>
<td></td>
<td>investigation</td>
</tr>
<tr>
<td>FSIS (meat &amp; poultry)</td>
<td>• Trace suspected foods back to source</td>
</tr>
<tr>
<td>FDA (most other foods)</td>
<td>• Assess production and processing facilities</td>
</tr>
<tr>
<td></td>
<td>• Ongoing prevention and monitoring efforts</td>
</tr>
</tbody>
</table>
Preparing for the future now

- Support for public health laboratories for WGS and reflex culture
- Epi investigative capacity for growing number of clusters
- Environmental micro assessments to find reservoirs and harborage
- Train current staff and attract new investigators and microbiologists

- Develop the next generation of diagnostic methods – getting all the information public health needs directly from the patient sample
- Develop sequence-based attribution and source prediction

- Turn surveillance data around faster, making it more useful than ever
- Translate into improved policies, practices, and prevention
The new world of public health whole genome sequencing

- Changes in laboratory workflow and workforce in public health
  - attracting a new generation of laboratory scientists
- Surge in detected clusters = more investigations
  - need more epidemiologists and environmental specialists
- "Big data" puts strain on IT infrastructure in state health departments and at CDC
  - need high speed web connections to transmit DNA sequence data
- The clinical world is using more culture-independent diagnostic tests (CIDTs) that do not yield a living bacterial isolate.
- Sequencing requires an isolate, so need to do “reflex culture” on CIDT+ specimens, and that work of culturing specimens is falling more and more on public health labs
  - until a future “metagenomic” advanced diagnostic test is developed that can obtain DNA sequence directly from a specimen without culture (5 – 10 years away?)
- WGS can be used for other pathogens – and it is in every state now
Incidence of diagnosed cases, by pathogen FoodNet, 1996-2018

- Active surveillance, part of Emerging Infections Program
- Collaboration among CDC, 10 FoodNet sites, FDA, USDA/FSIS
- 8 infections often spread through food
- Reliable and up-to-date data on illness trends
Continuous investment and improvement in public health laboratories

- Integrating WGS into the routine workflow in public health laboratories
- Building IT infrastructure: rapid internet upload speed is vital
- Adopting other new lab technologies, like mass spectroscopy

Clinical diagnostic labs continue to adopt “culture-independent diagnostic tests,” however, public health labs still needs to culture positive specimens to get isolates for WGS – These are necessary to find and investigate dispersed outbreaks & track success of control measures

This burden falls more and more on public health labs
Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Salmonella Trends: What the Science Tells Us

Kis Robertson Hale, DVM, MPH, DACVPM
Chief Public Health Veterinarian
CAPT, US Public Health Service
Deputy Assistant Administrator
Office of Public Health Science
Food Safety and Inspection Service
Salmonellosis incidence has been relatively flat

*Culture-confirmed includes those infections confirmed by culture only or by culture following a positive CIDT.

Source: CDC FoodNet Fast
Meat and poultry are known sources

Source: Interagency Food Safety Analytics Consortium (IFSAC) 2017 Annual Report
Questions recently investigated by FSIS

• What is the trend in *Salmonella* contamination in FSIS-regulated products since implementation of PR/HACCP final rule?

• How does this trend compare to the trend in human salmonellosis?
PR/HACCP Final Rule

- Pathogen Reduction/Hazard Analysis and Critical Control Point
- Published in 1996, phased implementation 1998-2000
- Required meat and poultry processors to develop and implement HAACP plans for preventing and controlling hazards
- FSIS responsible for conducting verification activities, including product sampling
FSIS sampling for Salmonella

- Product sampling is a key component of FSIS’ pathogen reduction strategy

- Almost 100,000 samples per year collected in slaughter and processing establishments

- Data obtained through sampling allows FSIS to:
  - Assess establishments against performance standards
  - Conduct baseline surveys to estimate industry-wide prevalence
  - Prevent adulterated product from entering commerce
  - Conduct surveillance
FSIS Pathogen reduction performance standards

- FSIS has set standards for *Salmonella* in raw meat and poultry products since 1998
- Developed using industry prevalence estimates and Healthy People goals
- Enable FSIS to verify establishments are consistently controlling bacterial hazards
- FSIS publicly posts establishment data and performance categories, leading to market pressure that drives pathogen reduction
Data sources

*Salmonella* prevalence estimates from baseline surveys (prior 1996)

Monthly FSIS verification testing data, 2000-2018 from:

Young chicken carcasses, ground turkey and ground beef
Downward trend in *Salmonella* contamination
Downward trend in *Salmonella* contamination
Downward trend in *Salmonella* contamination

Sample volume increase

New neutralizing broth as transport medium
Downward trend in Salmonella contamination

- Sample volume increase
- New neutralizing broth as transport medium
- Posting of establishments by performance categories
Downward trend in *Salmonella* contamination

- Introduced categorization
- Sample volume increase
- Posting of establishments by performance categories
- New neutralizing broth as transport medium
Conclusions

What is the trend in *Salmonella* contamination in FSIS-regulated products since implementation of PR/HACCP final rule?

- Substantial reduction in contamination relative to early to mid-1990s
- Chicken carcasses and ground products undergo >60% reduction despite 13-fold increase in sampling volume

How does this trend compare to the relatively flat trend in human salmonellosis?

- Product contamination rates have significantly declined; illnesses have not
Supporting analysis

• FDA NARMS *Salmonella* retail data analyzed

• Chicken breasts, ground turkey, ground beef, and pork chops collected at retail and tested during 2002-2017 (~100,000 samples)

• Compared to FSIS verification data around same time period

• Conclusions:
  • FSIS and NARMS trends in agreement from 2010-2017
  • Both show reduction in *Salmonella* contamination in all products, except pork
Takeaways

• Net decrease in *Salmonella* contamination in almost all raw major commodities since 1998

• Evidence that performance standards have been an effective tool

• Progress driven by multisectorial efforts:
  • USDA/FSIS
  • Federal partners (CDC, FDA, APHIS)
  • State/local agriculture and public health partners
  • FSIS-regulated industry
  • Retailers
But the job is not done…

- Static salmonellosis incidence suggests more work is needed to reduce pathogens in the food supply

- Science is key to addressing persistence food safety questions

- With increased technology, greater opportunities for innovative problem-solving

- Strong partnerships and collaboration continue to be vital
Reference

BREAK
Scientific Basis for Performance Standards

Denise Eblen, Ph.D.
Assistant Administrator
Office of Public Health Science
Food Safety and Inspection Service
U.S. Department of Agriculture
Outline

• What are performance standards?
• Why does FSIS have performance standards?
• How do we set performance standards?
• Have they been effective?
• Where do we go from here?
What are performance standards (PS)?

- PS are **microbiological cut-offs** that say how much contamination is too much.
- PS are *not codified regulations*; plants that make product with contamination above the performance standard may still produce.

Illustrative Example: Categories for Chicken Parts PS of 15.4% (~8/52)

- 12/52 ≈ 23% (Cat. 3 Not Meeting)
- 8/52 ≈ 15.4% (Cat. 2 Meeting)
- 3/52 ≈ 5.8% (Cat. 1 Meeting)
Why does FSIS have performance standards?

• Presence of non-adulterant pathogens, like *Salmonella*, in meat and poultry may result in human illnesses, hospitalizations and deaths

• Currently not practical to remove 100% of all pathogens - that is why meat and poultry need to be handled and cooked properly

• PS are designed to mitigate this risk, so it is as low as *reasonably possible*
Key factors in the design of performance standards

- Dept. of Health and Human Services publishes goals for reductions in preventable human illnesses (Healthy People (HP) Goals)
  - HP2030: 25% reduction in cases of salmonellosis
  - FSIS targets a 25% reduction in meat and poultry *Salmonella* contamination
- HP goal determines how stringent FSIS makes the PS
  - Public health risk assessment estimates the PS most likely to meet the HP goal
- Reductions in contamination must be technically feasible
  - If a significant part of the industry already has contamination levels below the PS, then it is technically feasible for everyone else to achieve those low levels
How are reduction targets determined?

Salmonella Illnesses from all food

Beef Salmonella Illnesses (~1M x 0.078)

Ground Beef (GB) Salmonella Illnesses (81K x 0.53)

HP2030 25% Salmonella Reduction (~42K x 0.25)

1.04M ~81K Beef

~42K GB 10 to 11K Target Illness Reduction

Poultry 19%

Pork 6%

Beef 7.8%

Non-FSIS regulated Foods 68%
How do we set performance standards?

HP 2030 25% Reduction
Application of performance standards by industry

• If a plant exceeds the allowable # positives in a 1-year moving window - i.e. does not meet the PS – it is considered Category 3
  
  • E.g. >8 *Salmonella* positives for chicken parts = Cat. 3 (PS = 8/52 ≈ 15.4%) Category status is publicly posted monthly

• However, plants with fewer than 52 samples collected may be subject to a less stringent PS: ‘adjusted’ %+
  
  • E.g. for chicken parts - smaller plants (producing ≤250K lbs./day) are assigned 2/month)
  
  • So, if only min # of samples collected (n=10) Parts PS = 2/10 ≈ 20%
Impact of performance standard category posting

- FSIS posts establishment categorization publicly to allow buyers of poultry *Salmonella* the necessary data to make purchases based on food safety.

- This approach has resulted in a market incentive based on food safety.

- From 2006-08 FSIS observed about a 55% drop in plants in Cat. 3 after announcing FSIS would publicly post *Salmonella* category status (Ollinger *et al*., 2017).
Have performance standards been effective?

- Effectiveness of PS can be measured by decreases in contamination

- Steady decline in *Salmonella* prevalence and % in Category 3 for chicken parts
  - 24% *Salmonella* prevalence to 8%
Where do we go from here?

- Linking HP goals to performance standards, and publicly posting *Salmonella* data has been effective in lowering *Salmonella* contamination in poultry

- FSIS plans a similar approach for ground beef/trim and ground/cuts of pork

- Improvements on the approach are always being considered
Peer-Reviewed Publications

• These papers discuss the theory and methods used to develop the HP2030 performance standard approach

• These papers discuss the application of the above methods
How FSIS Laboratories Support Efforts to Reduce Salmonella

William Shaw, Ph.D.
Executive Associate for Laboratory Services
Office of Public Health Science
Food Safety and Inspection Service
U.S. Department of Agriculture
So What Are We Doing in the FSIS Laboratories?

To address *Salmonella*, FSIS Laboratories continue to:

- Modernize sampling methods and adopt new approaches
- Modernize pathogen screening and confirmation methods
- Implement innovative uses of whole genome sequencing data
- Leverage cecal data to identify emerging *Salmonella* signals
- Collaborate with academic & research partners to reduce *Salmonella* 

*Agency Goal: Reduction in illnesses*
Modernize Sampling Methods: Catalysts for FSIS changes

- New technologies that can increase knowledge & decrease time
- Changes in industry and consumer practices
- Response to Public Health Challenges
- Stakeholder Feedback (AskFSIS, surveys, public input)
- New Research data from the scientific community
- Exploratory sampling projects and FSIS Lab method studies

Agency Goal: Prevent Foodborne Illness
Adopt New Approaches: Sampling Programs and Collection

• Use of neutralizing Buffered Peptone Water (nBPW) as sample collection and transport media
  Goal: Protect sample integrity from antimicrobial intervention residues

• Expanded sampling of high-risk raw product classes
  • Interim Products: Raw beef trimmings result data can assist process control determination, pork products, chicken parts and comminuted turkey products
  • Finished Products: Pork products, chicken parts and comminuted poultry products better represent consumer purchasing trends
  • Monitors sanitary conditions during production
    Goal: Improve process control in raw product classes and reduced pathogen occurrence
Adopt New Approaches: Outreach and On the Horizon

- **Collaborate with industry**
  - FSIS lab staff consulting with establishment’s lab methods
  - Industry visiting FSIS labs and Open Houses
  - Provide lab method feedback to industry

  **Goal:** Improve establishment’s methods and lab procedures to enhance pathogen detection during production

- **Upcoming Initiatives**
  - Improving sample shipment procedures
  - Alternative sample collection techniques for N60 type raw beef and raw poultry rinses and swabs
  - Accredited Laboratory Program (ALP) expansion into microbiology
Modernized Salmonella Screening – January 2019

MLG 4 Salmonella methodology

• Utilizes rapid loop-mediated isothermal DNA amplification (LAMP) rapid screen technology
• Compact platform saves space for expansion and testing
• A brief, user-friendly setup provides fewer opportunities for errors and contamination
• Fast lysis time and high accuracy in a high throughput environment
• Detection as low as 1 CFU per sample
• Reduced run time from 3-4 h to ~40-45 min or less
Continue to Modernize Salmonella lab methodologies—On the Horizon

FSIS will continuously explore innovations and technologies to support Salmonella testing programs:

- Identification of more pathogenic *Salmonella* at the 2nd day screening stage to support product usage decisions
- Proteomics with biochemistry to confirm isolates (15 min v. 24 h)
- High throughput adaptive enumeration analyses
- Strategic usage of indicator data
- Strengthen bioinformatic tools
Implement innovative use of whole genome sequencing data to address *Salmonella*– Connecting the Dots

- NCBI AMRfinder plus analyzes WGS data uploaded to NCBI to identify antimicrobial resistance genes, stress response genes, and virulence genes.
- WGS data analyzed includes not only WGS data from FSIS isolates, but also from public health laboratories, academic laboratories and research laboratories.

### Antimicrobial Resistance Genes

- Acquired resistance
- Point mutations

  Examples: *blaCTX-M-65, qnrB-19, gyrA_D87G*

### Stress Response Genes

- Heat resistance
- Acid resistance
- Sanitizer resistance

  Examples: *qacEdelta1, merR, hsp20*

### Virulence Genes

- Pathogenicity islands
- Adhesion and invasion
- Type III secretion systems

  Examples: ????
Implementing Whole Genome Sequencing Data

- FSIS, via GenFS, is actively working with public health partners to identify *Salmonella* virulence genes to include in AMRfinder Plus.

- GenFS is considering to curate a list of informative genes, rather than all virulence genes.

- Additional genes will be added to NCBI AMRfinder plus, if necessary.

- Unlike Shiga toxin-producing *Escherichia coli* (STEC), there are not typically two or three genes that define virulence
  - Need to consider redundancy and additive effects toward virulence

**Virulence Genes**

- Pathogenicity islands
- Adhesion and invasion
- Type III secretion systems
- Examples: ????

**COMING SOON FOR SALMONELLA**
Implementing Whole Genome Sequencing Data

• Virulence genes may be used to predict a higher likelihood of severe illness.

• Virulence genes may be used to determine appropriate product usage.

• Stress genes may be used to predict likelihood of survival in environments and can be used to evaluate intervention strategies.

• Gene content may be used in commodity attribution models during outbreak investigations.

• Gene frequencies may be used to identify additional targets to screen for specific subtypes.
Collaborate with academic and research partners to reduce *Salmonella*

- FSIS promotes public health and regulatory initiatives on *Salmonella* using Research Priorities
- FSIS Eastern Laboratory provides bacterial isolates and genomic data from its vast library to support research
  - [scientificliaison@usda.gov](mailto:scientificliaison@usda.gov) for information on the process
Examples - Bacterial Isolate Transfers Support Research Priorities

- Investigate and/or develop emerging screening technologies to reduce time for detection
  - Multiple serotypes to test kit manufacturers

- Determine the presence and contributing factors for antimicrobial resistant strains in poultry and cattle
  - S. Infantis strains to USDA ARS, academic and industry partners

- Identify unique attributes of pathogen outbreak strains that may increase the probability of foodborne illness.
  - S. Reading strains to USDA ARS partners and University of Minnesota

- Determine (validate) the effectiveness (log-reduction) of interventions used by industry to reduce levels of pathogens on FSIS regulated products.
  - Various serotypes for heat resistance studies at USDA ARS and academia
Leverage NARMS data to identify pre-emergent *Salmonella*

Provide monthly snapshot of changes within serotypes and antimicrobial resistance
Leverage NARMS data to identify pre-emergent *Salmonella*

- In FY2020 in collaboration with FDA, FSIS implemented NARMS Expansion
  - View into antimicrobial and pathogen burden of additional animal sources
  - Testing for *Salmonella* in mesenteric lymph nodes for cattle in new slaughter classes (goat/lamb/sheep and veal cecal materials)
Summary

FSIS is fully committed to using science-based approaches to reduce Salmonella illness as follows:

• Continuous FSIS lab methodology improvements: speed, accuracy, and depth of information obtained from testing.

• Continuous improvements of industry affiliated labs and methods employed

• Collaborate with public health and research partners to identify Salmonella genes associated with source attribution, survival, and virulence.

• Use cecal data to proactively identify trends in serotype, antimicrobial resistance, etc. before they are considered emergent.
Role of Science in Modernizing Inspection Systems

Philip Bronstein, Ph.D.
Assistant Administrator
Office of Field Operations
Food Safety and Inspection Service
U.S. Department of Agriculture
Food Safety and Inspection Service

FSIS Inspection

6,479 Establishments, 133 Import/Inspection houses, and 150,000 In-Commerce Facilities Nationwide
Modernization in FSIS

• Goal of Modernization:
  • Build on the Hazard Analysis and Critical Control Points (HACCP) system principles established in the 1990s
  • Leverage inspection/food safety data collected in FSIS regulated plants
    • Over 100 years of Inspection
    • Over 20+ years of HACCP
    • About 20 years of HIMP
  • Focus on inspection tasks that directly impact public health and food safety hazards
Modernization

- Focuses on reduction of microbes on products
  - Establishments required to test for bacterial indicators at two points in process
  - There is a relationship between the change in bacterial indicators and the presence of *Salmonella* on products
- Removes unnecessary regulatory obstacles to industry innovation.
- Optional update to slaughter inspection approach
  - Establishment personnel sort prior to FSIS inspection
  - Increases the effectiveness of slaughter inspection
  - Optimizes the use of FSIS resources
- FSIS continues to perform inspection on 100% of all livestock prior to harvest and every carcass in all inspection systems
Microbial Testing under PR/HACCP Rule

• The rule required slaughter establishments:
  • Test carcasses for generic *E. coli*
  • At a single point in the process
  • At a specific frequency
  • Specified a sampling method

• Established Acceptable, Marginal, or Unacceptable levels

• May have encouraged industry to focus primarily on post-slaughter interventions, rather than prevention and mitigation of microbial contamination throughout the slaughter process.
Modernized Slaughter Microbial Testing

• Removed codified *Salmonella* performance standards and generic *E. coli* testing requirement.

• The rules require slaughter establishments:
  • Test carcasses for an indicator organism
  • At two points in their production process
  • At a specific frequency
  • No sample method specified
Modernized Slaughter Microbial Testing

• The new testing requirements allow establishments to develop sampling plans that are more tailored, thus more effective, in monitoring their specific process control.

• FSIS Inspectors verify that the establishment microbial program results support process control.
Indicator Organisms

• Sampling requirements – Microbial Indicator Organism

• Each establishment sampling program identifies the specific microbiological organisms (i.e., *Salmonella*, *Campylobacter*, or other enteric organisms) for which the establishment will test to monitor the effectiveness of its process control procedures.

• Indicator Organism such as:
  • aerobic plate count (APC), total coliform, Enterobacteriaceae, and
  • *Escherichia coli*, Biotype I, also known as generic *E. coli*. 
## Multiple Point Sampling

### Table 1 - Indicator Organism Median Values for Chickens

<table>
<thead>
<tr>
<th></th>
<th>Generic E. coli</th>
<th>APC</th>
<th>Enterobacteriaceae</th>
<th>Total Coliform</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcass – Rehang</td>
<td>540</td>
<td>28,000</td>
<td>1,600</td>
<td>940</td>
</tr>
<tr>
<td>Carcass – Post Chill</td>
<td>20</td>
<td>260</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

### Table 2 - Indicator Organism Median Values for Turkeys

<table>
<thead>
<tr>
<th></th>
<th>Generic E. coli</th>
<th>APC</th>
<th>Enterobacteriaceae</th>
<th>Total Coliform</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcass – Rehang</td>
<td>22</td>
<td>1,800</td>
<td>50</td>
<td>40</td>
</tr>
<tr>
<td>Carcass – Post Chill</td>
<td>&lt;1.2</td>
<td>18</td>
<td>&lt;1.2</td>
<td>&lt;1.2</td>
</tr>
</tbody>
</table>

From June 2015 FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection
Assessing Process Control

• Compare tests results to baseline results
• Identify and investigate outliers
• Determine root cause
Biomapping

- Biomapping options
  - Multiple points in the process (6-7)
  - Can demonstrate effectiveness of multi-hurdle approach

Bio-map of evisceration. The bacterial mean log CFU/mL counts for both Enterobacteriaceae and aerobic plate counts (APC).
Modernized Slaughter Post-mortem Inspection

• In NPIS and NSIS, FSIS on-line inspectors continue to provide 100% carcass-by-carcass post-mortem inspection.

• FSIS off-line inspectors perform twice as many hands-on checks of carcasses to verify the absence of visible feces, ingesta, and milk (pork only); the materials known to be associated with Salmonella and other enteric pathogen contamination.

• Both on-line and off-line FSIS inspectors ensure the establishment maintains process control throughout slaughter.
LUNCH
Welcome Back and Housekeeping

Shayla Bailey
Moderator, FSIS, USDA
Role of Science in Consumer Research and Education

Carol Blake
Assistant Administrator
Office of Public Affairs and Consumer Education
Food Safety and Inspection Service
U.S. Department of Agriculture
Two-Pronged Approach to Food Safety

In-Plant Inspection

Safe Food Handling
Influence Behavior Change

2020 Vision

- Promote consumer education of safe food handling practices
- Use easy-to-understand communications
- Reduce *Salmonella* and other foodborne illnesses
Consumer Education Over Time
Changing Landscape of Consumer Education at FSIS

Communication Obstacles:

- New Channels
- Divided Attention
- Perceived Risk
- Misinformation
Consumer Research Studies

Consumer research is the backbone of FSIS’ educational outreach

- **Observational Studies**: 5 ongoing
- **Focus Group Research**: 2 ongoing
- **Web Based Surveys**: 2 ongoing

Applying Findings to Food Safety Messaging

Handwashing Findings

Participants failed to properly clean their hands up to 99% of the time

FSIS Response

Focus attention on the ‘clean’ food safety step
Applying Findings to Food Safety Messaging

Cross-Contamination Findings

Unsafe food handling can spread Salmonella from raw meat and poultry to ready-to-eat foods

FSIS Response

Updated consumer messaging: Poultry washing increases risk because it spreads pathogens in the sink
Implications of this Research

**Clean**
Wash hands and surfaces often.

**Separate**
Separate raw meats from other foods.

**Implications of this Research**

**Clean**
- **Hand Washing**
  - Rate of Failure: 99%
  - Always wash your hands for at least 20 seconds with soap and water.

**Separate**
- **Separate Your Food**
  - Decrease risk by preparing foods that will not be cooked such as veggies and salads, before handling and preparing raw meat and poultry.

**Implications of this Research**

**Washing Poultry**
- Risk of Contamination: 60%
  - 60% of participants contaminated the inner sink when they washed chicken.
  - The safest choice is not to wash meat or poultry.
Implications of this Research

Observational Meal Preparation Experiment

22% of participants were unaware that the not-ready-to-eat (NRTE) frozen chicken they prepared was raw

Web-Based Survey

61% of respondents who have had foodborne illness did not make changes to how they prepared food at home
Partnerships

FSIS works with partners to explore novel ways to educate consumers and conduct consumer research.
Advancing Public Outreach

UPCOMING EVENT
October 6, 2020

The U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) is holding a virtual public meeting on Oct. 6 to discuss the state of consumer food safety education, current research, and future studies and engagement to close the gap between food safety messages and consumer action.
Discover Food Safety Resources

www.fsis.usda.gov
www.foodsafety.gov
USDA Meat and Poultry Hotline
1-888-MPHotline
(1-888-674-6854)
Roundtable Discussion

Shayla Bailey, Moderator, FSIS, USDA
Panelists

Carol Blake
Philip Bronstein
Melvin Carter
Rachel Edelstein
Emilio Esteban
Kis Robertson Hale
Sheryl Shaw
Janet Stevens
Joanna Zablotsky Kufel
Role of Research at FSIS

Isabel Walls, Ph.D.
Senior Public Health Advisor and Scientific Liaison
Office of Public Health Science
Food Safety and Inspection Service
U.S. Department of Agriculture
FSIS Research Priorities/ Studies

• Science-based food safety regulatory agency
  – Not a research agency
• Identify new research priorities annually, based on
  – Outbreaks
  – Laboratory data
  – Findings in the field
  – FSIS Hazard Identification Team
• Communicate to sister agencies/ wider scientific community
  • Detailed studies provided for many priorities
  • Work is underway for many priorities and studies
Accomplishing Research Goals

• FSIS accomplishes research goals through partnerships and collaborations
  – USDA’s Agricultural Research Service
  – NIFA/ Academia
  – ORISE fellow

• We share research findings through publications, seminar series, webpage

FSIS has 18 Research Priorities in 4 Categories

- Chemicals of Potential Concern
  - Screening/ Detection methods
  - Chemical Characterization
  - Intervention Strategies
- Biological Hazards
  - Screening/Detection/Enumeration Methods
  - Pathogen Characterization
  - Intervention Strategies
- Animal Welfare
- Label verification
Screening/ Detection/ Enumeration Methods

• Priorities
  – Develop methods to reduce pathogen detection time
  – Develop methods for detection of multiple pathogens from a single sample
  – Develop methods for quantifying pathogens

• Studies
  – *Salmonella* in pre-harvest poultry
  – *Salmonella* when multiple serotypes are present
  – *Salmonella* in meat, poultry, and egg products
Pathogen Characterization

• Priorities
  • Improve our understanding of antimicrobial resistance in pathogens in poultry and cattle
  • Develop technologies for enhanced virulence/pathogenicity characterization of pathogens

• Studies
  • Investigate acquired antibiotic resistance in *Salmonella*
  • Evaluate biocide resistance of outbreak vs. non-outbreak *Salmonella* strains
Pathogen Characterization

• Priorities
  • Determine contribution of extra-intestinal sources of pathogens to contamination of FSIS-regulated products

• Studies
  • Determine the contribution of *Salmonella* from swine lymph nodes to contaminated ground pork
  • Determine prevalence, load and strains of *Salmonella* in raw chicken livers
Pre- and Post Harvest Intervention Strategies

• Priority
  • Develop/ evaluate effectiveness of pre-harvest interventions to reduce pathogens

• Study
  • Determine whether differences in poultry-rearing practices influence microbiological profile of poultry carcasses
Intervention Strategies for low moisture foods

• **Priority**
  • Develop/ evaluate the effectiveness of post-harvest interventions, e.g., to reduce pathogens in low moisture foods

• **Study**
  • Estimate drying times for different diameter dry/ semi-dry fermented sausages to ensure a 5-log reduction of Salmonella
Intervention Strategies at retail and for consumers

• Priorities
  • Identify consumer/retail practices which compromise the safety of FSIS regulated products
  • Generate data to develop public education/outreach to improve food-handling practices

• Studies
  • Identify critical operational parameters to control *Salmonella* in rotisserie chicken cooked at retail
  • Investigate preparation practices that result in undercooking of chicken livers and identify practices that reduce public health risk while maintaining desired properties of chicken livers
FSIS research priorities website

• By communicating FSIS Research and Data Priorities, we hope to:
  • Encourage researchers to apply their expertise to address FSIS priorities
  • Encourage research funding agencies to consider FSIS priorities when developing research opportunities

ARS Mission and Role

Non-regulatory, intramural research arm of USDA

Solution oriented, hypothesis-driven research that delivers solutions to agricultural issues of national priority

Novel research to address priority food safety issues across the food production and processing continuum

Multidisciplinary, systems-based approach
Food Safety as an ARS Mission Priority

- Ensure high-quality, safe food, and other agricultural products
- Assess the nutritional needs of Americans
- Sustain a competitive agricultural economy
- Enhance the natural resource base and the environment, and
- Provide economic opportunities for rural citizens, communities, and society as a whole
ARS Food Safety Research: Salmonella

- 14 Locations
- Currently 50 projects
  - 28 Salmonella
- 174 Ph.D. scientist positions (40 vacancies)
- ~$21 million investment
What? How? Where?

What are the gaps of highest priority?
How do we most effectively address the gaps?
Where is the research taking us?
Screening/ Detection/ Enumeration

Identify and evaluate improved sampling methods
Develop or refine technologies to reduce pathogen detection time
Develop or refine technologies to detect multiple pathogens
Develop or refine testing methods for quantifying pathogens
Innovative Detection Technologies

- Novel capture device for the rapid and cost-effective separation of bacteria from complex food matrices
- Rapid, portable, label free sensor capable of detecting foodborne pathogens in food
- Rapid detection of *Salmonella* Typhimurium in large volume samples using porous electrodes in a flow-through, enzyme-amplified immunoelectrochemical sensor
- Direct typing of enriched samples using targeted-sequencing
Reimagining how we test for *Salmonella* in foods: Contamination Level and Pathogenicity Level

Quantitative data to improve HACCP analysis and decrease human exposure

Developed rapid, semi-quantitative method for estimating *Salmonella* contamination levels

Characterized starting contamination level (CFU/g) and corresponding detection time or Time-to-Positivity (TTP)

Multiplex assay to target **Highly Pathogenic Salmonella (HPS)**

**DENT** - Dublin, Enteritidis, Newport, Typhimurium, and O 1,4,[5],12:i:-
Novel Method for Nondestructive Sampling of Raw Beef Trim

Continuous Sampling Device (CSD)

Manual Sampling Device (MSD)

• Improved sample collection methods for foodborne pathogens
  o Samples a larger surface area of product
  o Nondestructive
  o Rapid (minimal employee sample collection time)

• Validation trials for Shiga toxin-producing *E. coli* and *Salmonella*

• Developed and commercialized with industry partner

• In use by numerous beef processing companies

• Ongoing validations of efficacy for pork and poultry sampling
Flock Gut Health Surveillance System - Overview

Salmonella Surveillance System

Data Transfer

Web Server

Data Transfer

Mobile Network (Tablet, Smart Phone)

Send to push message

Send to alarm

Tablet, Smart Phone

Farmer

Poultry Farm Monitoring using Smart Phone App (Potential Birds with GI compromise)

Cameras

US National Poultry Research Center, Athens, GA
Pathogen Characterization

Develop or refine cooking and cooling models for pathogens in foods
Determine the contribution of endogenous extra-intestinal sources of pathogens (e.g., lymph nodes) to contamination of FSIS-regulated products
Develop or refine technologies for virulence/pathogenicity characterization of pathogens
Improve our understanding of antimicrobial resistance in pathogens in poultry and cattle
Process Validation – Ready to Eat and Specialty Foods

- *Salmonella* in chicken livers
  - Quantified recovery rate and fate
  - Established “true prevalence” in chicken livers
  - Contributed to cooking guidelines for pâte

- *Salmonella* from matched swine fecal and carcass samples
  - Showed each lot of swine introduced new contaminants into plant
  - Feces from one animal can contaminate many carcasses
  - Swine abattoir operated effectively under HIMP system
Salmonella Enteritidis Invasion of Internal Organs and Contamination of Eggs

Assess *S*. Enteritidis invasion of internal organs and contamination of egg contents

Experimentally infected laying hens of four commercial genetic lines in conventional cages or enriched colonies
S. Enteritidis Recovery from Infected Hens and Eggs

Significant differences between genetic lines of hens

Minimal effects of the two housing systems
Salmonella enterica serovar Reading

- *S.* Reading outbreak in raw turkey 2017-2019
  - 358 human infections reported
  - 133 hospitalizations, one death

*How did Reading change and did changes affect its fitness?*

- Genomic comparisons of turkey-associated isolates: Pre-outbreak versus outbreak
- Phenotypic characterization of isolates: Turkey challenge study
Genome Sequence Comparison of S. Reading isolates: Gene Presence vs Absence

- Genetic variation was observed between the isolates from pre-outbreak and outbreak
- Genome reduction pattern was observed in outbreak isolates and from human isolates of Reading
- Genetic differences are in genes that could contribute to variation in *Salmonella* fitness or virulence

*Bacteriophage-like genes and genes encoding hypothetical proteins*
Turkey challenge study to evaluate colonization, dissemination and persistence

- Two day old poults were orally inoculated with one of the 5 selected Reading strains
- At 1, 3, 5 weeks post-challenge, 12 turkeys (more at week 5) were euthanized to evaluate *Salmonella* levels in the ceca, Bursa of Fabricius and spleen

- Colonization and persistence in the turkey was significantly *greater* in the turkeys challenged with the 2016 pre-outbreak isolates compared to the 2019 outbreak isolates
Salmonella Infantis

In the United States *Salmonella* Infantis is often associated with poultry.

More than 85% of Infantis isolates from chicken and turkey carry the plasmid with genes for resistance to antibiotics, metals and biocides.

Many of the plasmids carry genes that may provide the bacterium an advantage in the chicken or in processing.

Next Steps...
Pre-harvest and Post-harvest Interventions

Identify and/or develop and evaluate the effectiveness of pre- and post-harvest interventions to reduce levels of pathogens in FSIS regulated products
Pre-Harvest Intervention and Control Strategies

• **Approach:**
  - Modulation of innate immunity: trained immunity
  - Microbiota manipulation
  - Interactions at Host - *Salmonella* - Gut Interface
  - Alternatives: Microbial metabolites; phytochemicals, dietary additives
  - Proteomics & metabolomics
  - Microbiota and mucosal immunity

• **Goal:**
  - Limit colonization with foodborne pathogens
  - Optimize gut microbiota
  - Inform best practices
S. Heidelberg in Fresh and Re-used Litter

Reduced S. Heidelberg survival in reused litter (14 days)

More susceptible S. Heidelberg strains in reused litter

US National Poultry Research Center, Athens, GA
Post-harvest: Interventions and Control Strategies

- Pulsed Electric Field/Light
- Radio Frequency
- High Pressure
- Mild Heat & SLIC
- Cold Plasma
- Sensing: hyper/multispectral/Raman
Where Does the Research Go?

- Systems approaches, multi-hurdle interventions and alternative biocides
- Genomics, metabolomics and food animal-pathogen-gut associations
- Predictive microbiology and risk science
- Overcoming the threshold with new approaches
- Machine learning, Remote sensing with sUAVs (small Unmanned Aerial Vehicles)
Holistic Approaches to Address Persistence and Dissemination of Pathogens and Antibiotic Resistance

US National Poultry Research Center, Athens, GA

Intervention Strategies for Food Safety

- Mitigate AMR transmission
- Decrease antibiotic usage
- Analyze microbiota development and disturbance
- Develop methods to modulate microbiota and host immunity
- Reduce carriage

National Animal Disease Center, Ames, IA

- Reduce carriage
- Decrease antibiotic usage
- Mitigate AMR transmission
- Analyze microbiota development and disturbance
- Develop methods to modulate microbiota and host immunity

USDA
AGRICULTURAL RESEARCH SERVICE
Hypothesis: Broiler chicks or litter infected with *Salmonella* carry a unique microbiota that differentiates them from uninfected chicks or litter
Hypothesis: Broiler chicks carrying *Salmonella* will peck more and metabolize food better than naïve broiler chicks.

Phase I of 3:
- Compare performance and microbiome of chicks infected with *S. Heidelberg*
- Tested the accuracy of vb for counting and identifying broiler chickens in feeding and drinking zone (Guo et al., 2020)
  - Machine learning (Neural network model)
- Test and optimize vb under *S. Heidelberg* infection and litter management practices (on-going).
Salmonella Metabolic Modeling to Predict Strains that are a Threat to Human and Animal Health

Genome Sequence:
Series of genes on a chromosome or plasmid

Pathway Tools Database

Metabolic Models:
Predict genome-wide flow of metabolites in bacterial systems

Static Reference
What a genome is

Dynamic Reference
What a genome does
Predictive Microbiology & Data for Risk Assessment

- ComBase: A USDA web resource for quantitative and predictive food microbiology
- Predictive microbiology models that have validity & relevance to “real food systems”
- Translating these data into mathematical models & user-friendly software tools
- Risk models are essential to determine the human impact of foodborne pathogens and antimicrobial resistance to public health
  - Quantitative data are needed to fill gaps
Final Thoughts

Identify solutions that overcome food safety and food security issues posed by continued persistence of *Salmonella*

Systems-based, multi-disciplinary research within ARS national programs and with University, Industry and Federal partners

**What** are the gaps?

**Where** are the critical control points for interventions?

**How** do we apply them across the food continuum?
THANK YOU!

Feel free to contact us for more information:

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Future Challenges and Opportunities

Mindy Brashears, Ph.D.
Under Secretary for Food Safety
U.S. Department of Agriculture
FSIS Wrap-up: Future Opportunities and Challenges

Mindy Brashears, PhD, Under Secretary for Food Safety, USDA
Lead with Science
Technology and Innovation
Lead with Science
Modernized Beef Inspection
Lead with Science
Salmonella Enumeration
Lead with Science

Food Safety Fellowship
Build Relationships
Small Plant Outreach
Congressional Roundtables
Influence Behavior Changes
Consumers
Public Comment
Pre-registered Public Comment

Shayla Bailey,
Moderator, FSIS, USDA
Public Comment Period
Pre-registered speakers

1. KatieRose McCullough, North American Meat Institute
2. Sandra Eskin, The Pew Charitable Trusts
3. Jamie Jonker, National Milk Producers Federation
4. Afreen Sultana, Jamia Hamdard University
5. Mitzi Baum, Stop Foodborne Illness
6. Sherri Williams, JBS USA Food Company
7. Thomas Gremillion, Consumer Federation of America
8. Martin Wiedmann, Cornell University
9. Catherine Alinovi, Next Generation Pet Food Manufacturers Association
10. Sarah Sorscher, Center for Science in the Public Interest
Public Comment Period
Pre-registered speakers

11. Marybeth Yannessa, Refrigeration Technologies LLC
12. Kara Morgan, Ohio State University, Center for Foodborne Illness Research and Prevention
13. Daniel Kovich, National Pork Producers Council
14. Panayiotis Andreou, HSI Foodtech Labs Ltd
15. Lynnette Thompson, Tell All the Truth
16. Salman Rizvi, Al Arkkan Training Center, KSA
17. Ken Koehler, Stop Foodborne Illness
18. Thomas Hill, Virginia Department of Health, New River Health District
19. Kristi Smedley, Center for Regulatory Services, Inc.
20. Chelsea Kent, Food Regulation Facts Alliance
Public Comment Period
Pre-registered speakers

21. Wrayanne Cruz, Albertsons

22. Barbara Kowalcyk, Ohio State University, Center for Foodborne Illness Research and Prevention

23. John Lopes, Microcide, Inc.

24. Christos Gougoulias, Innovad

25. Steven Mandernach, Association of Food and Drug Officials

26. Jonathan Sierra, Yarok Microbio

27. Akinniyi Dare, Avian Resources Development and Services

28. Michael Martin, NC Department of Agriculture and Consumer Services, Veterinary Division

29. Amit Kheradia, Remco Products Corp

30. Eileen Ferraro, SDSMS
Public Comment Period
Pre-registered speakers

31. John Davidson, D.R.E
32. Barbara Kero, FSIS Stakeholder
33. Stanislaw Franczak, FSIS Stakeholder
34. Twan Koenen, IWC International
35. Sabrina Osterwalder, Studer Maschinenbau AG
36. Savi Subra, Savvy MicroConsultancy
37. Jeff Swartz, Corvium, Inc.
38. Brittany Rowe, Animal Law Litigation Clinic
39. Diana Goodpasture, Stop Foodborne Illness
40. Chris Schoch, Rayfresh Foods
Public Comment Period

Pre-registered speakers

41. Carl Custer, FSIS Retired

42. Renzo Gomez, Quantum Food Solutions Inc.

43. James Byrd, Agricultural Research Service, USDA

44. Madeleine Kleven, Keep Antibiotics Working

45. Kohl Harrington, Harrington Films

46. Linda Roberts, FSIS Stakeholder

47. Angela Anandappa, Alliance for Advanced Sanitation

48. Olaniyi Olayiwola, NICERT LIMITED

49. Ruth Jewkes, Anitox
Closing Remarks

Terri Nintemann, Deputy Administrator, FSIS, USDA