



United States Department of Agriculture

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service (FSIS)

FSIS Policy Overview

WGS Public Meeting

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Food Safety and Inspection Service:

Why FDA and FSIS May Approach the Use of WGS Differently in the Regulatory Arena Aside from Outbreak Response

FDA, FSIS regulate different foods, different associated risks, different consumption/exposure rates

- FSIS regulates raw meat and poultry and NRTE/RTE meat and poultry, egg products
- FDA: raw/cooked fish * and shellfish, raw shell eggs, raw fruits and vegetables, NRTE/RTE food ingredients, RTE processed foods

FSIS/FDA domestic establishments numbers, inspection frequencies differ

- FSIS (FMIA, PPIA, EPIA)
 - Over 6000 establishments, slaughter /processing establishments
 - Continuous inspection for slaughter, egg products establishments, inspection once per production shift for processors
 - Weekly meetings between establishment management/FSIS in plant personnel
- FDA (FSMA)
 - Over 60, 000 establishments
 - Inspection: Once every 3 years HR establishments, once every 5 years LR establishments
 - States assist FDA to meet/exceed the minimum inspection frequencies

Food Safety and Inspection Service:

Why FDA and FSIS May Approach the Use of WGS Differently in the Regulatory Arena Aside from Outbreak Response

- **FSIS/FDA have different sampling models in domestic establishments**
 - **FSIS:** In plant inspectors collect thousands of regulatory samples to verify HACCP systems are working, establishments are meeting pathogen reduction performance standards where applicable thus maintaining process control; for cause environmental sampling in RTE establishments
 - **FDA**
 - Collects environmental samples in domestic arena at RTE establishments; for cause product samples also collected
 - FDA/FSIS do collect product samples to establish prevalence baselines
- **Both FSIS/FDA have progressive enforcement tools established through laws/regulations**
 - FSIS field takes actions including suspension of inspection at establishments (they cannot legally operate); FDA even Warning Letters require HQ/OGC approval
- **FSIS will likely utilize WGS in a different manner than FDA in the regulatory arena with the exception of outbreak response as a result**

Food Safety and Inspection Service:

How are we using WGS data to protect public health?

During Outbreak Investigations: With PFGE, WGS plays an important role by enhancing the accuracy of detecting true cases and identifying the true cause of an outbreak (↑sensitivity and specificity)

Advantages:

↓ chance of misidentifying an outbreak source

↑ opportunity to detect outbreak/outbreak source earlier with fewer cases

↑ accuracy/better scoping of a recall

Importantly, FSIS and public health partners will continue to rely on epidemiological data and product distribution records/traceback to confirm these associations. FSIS will continue to follow procedures from [Directive 8080.3](#) Foodborne Illness Investigations

Food Safety and Inspection Service:

How are we using WGS data to protect public health?

REACTIVE - Identifying Evidence of Harborage: Along with PFGE, WGS can provide evidence of harborage, and in some cases repeated introduction of a strain into a food production environment or cross-contamination,

Advantage: WGS enhances accuracy for identifying these events; provides actionable information to help industry take corrective actions; corrective actions taken in response to harborage may have to be different/more robust

FSIS has been communicating evidence of harborage/persistence in particular to establishments; FSIS will develop procedures for reporting evidence based on WGS data, and working with FDA to assess data from dual jurisdiction establishments (DJE)

Food Safety and Inspection Service:

How could we use WGS data to protect public health?

PROACTIVE: Evaluate Long Term or Industry-Wide Trends: Some potential applications discussed in this meeting:

- Novel and recognized AMR genes in *Salmonella*, *Campylobacter*, generic *E. coli* and *Enterococcus* spp.
- Subtype distribution in animal species, products or global geographic regions
- Presence/absence of pathogenicity islands or genes associated with STEC, *Salmonella*, *Campylobacter*, and *Listeria monocytogenes*
- Presence/absence of genes associated with resistance to commonly employed interventions (antimicrobials, pH, heat)

Major Policy Questions: How would these results influence the design of future exploratory or baseline studies conducted to determine need to set/modify performance standards, categorization of establishments relative to meeting/not meeting performance standards, sampling programs, lab detection methods, risk assessments and attribution measures

Food Safety and Inspection Service:

How could we use WGS data to protect public health?

Evaluate Data from Individual Establishments (aside from positive sample rate):

- Pathogen lineages historically associated with outbreaks or illness
- Presence of pathogenicity islands, genes, or gene combinations associated with virulent strains
- Presence of genes associated with resistance to antibiotics, antimicrobials, and commonly employed interventions

Major Policy Question: How should these data influence the level of concern and subsequent assignment of Agency resources (follow up samples, public health risk evaluation (PHRE), food safety assessment (FSA), enforcement?)

Food Safety and Inspection Service:



Federal Register / Vol. 81, No. 28 / Thursday, February 11, 2016 / Notices

7285

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2014-0023]

New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

poultry, and egg products is safe, wholesome, and properly labeled and packaged.

As FSIS explained in the January 26, 2015 (80 FR 3940), **Federal Register** notice (“January 2015 notice”) in which the Agency proposed the new pathogen reduction performance standards, *Salmonella* and *Campylobacter* bacteria are among the most frequent causes of human foodborne illness in the United States. Currently, events that cause contamination of raw carcasses cannot be eliminated through the commercial production and slaughter practices employed by the U.S. industry. Contamination can be minimized,

products on June 1, 2013.¹ The Agency posted the aggregate results of this testing as part of its quarterly *Salmonella* report.²

In addition, FSIS conducted the Nationwide Microbiological Baseline Data Collection Programs: Raw Chicken Parts Baseline Survey, from January 2012 to August 2012, to estimate the percent positive of various raw chicken parts sampled and the levels of *Salmonella*, *Campylobacter*, and indicator bacteria on these products. FSIS used this information to estimate the national prevalence of *Salmonella* and *Campylobacter* in four pound portions of raw chicken parts. An

FSIS will schedule a Public Health Risk Evaluation (PHRE), and possibly a Food Safety Assessment (FSA), based on FSIS test results, for establishments that do not meet the pathogen reduction performance standards; for establishments that have produced products with repetitive *Salmonella* or *Campylobacter* serotypes of public health concern or repetitive antibiotic resistant *Salmonella*; and for establishments with *Salmonella* or *Campylobacter* pulsed-field gel electrophoresis (PFGE) (or whole genome sequencing, as it becomes available) patterns matching those found in recent outbreaks or epidemiologically linked to illnesses.

Food Safety and Inspection Service:

Summary

- **WGS technology is a critical component of the Agency's 5 year Strategic Plan**
- **WGS improves on PFGE's ability to detect and confirm clusters**
 - **FSIS is using WGS data to detect clusters potentially representing outbreaks or incidents of harborage, and is developing procedures for reporting results directly to establishments**
- **WGS provides unprecedented ability to characterize pathogen isolates. FSIS can use these data to**
 - **Understand temporal, geographical, or industry specific trends**
 - **Enhance sampling programs, pathogen detection methods, and risk assessment/attribution studies, and ultimately food safety policies**
 - **Understand establishment-specific results to prioritize the assignment of Agency resources**
- **Establishments can use the results to inform design and verification of HACCP system controls and supply chains**
- ***Need to proceed cautiously at we look for other uses for WGS in the regulatory arena***

Food Safety and Inspection Service:

Summary of Public Meeting Key Points

- **WGS is one tool, must be used in combination with other evidence/data**
- **WGS will change how we define/characterize hazards; e.g. is all Salmonella not equal?**
- **Chain of transmission of pathogens, gene expression, environment, food matrix/production all must be considered when looking at WGS data**
- **Need standardization/harmonization across all Networks relative to WGS meta data, data reporting, analytics tools (availability of web based, easy to use tools needed) , interpretation of data;**
- **Need to develop and follow data quality standards**
- **Need training to assure consistency in data interpretation**
- **All stakeholders need to continue to communicate , collaborate, learn together, share, through multiple venues/forums**
- **Can we create a safe harbor for industry to use WGS; use of third party labs /entities /Voluntary Net suggested**
- **We need to very deliberately move forward using WGS in regulatory arenas**

Food Safety and Inspection Service:

Perspectives: Roundtable

- **Welcome to roundtable participants:**

Dr. Martin Wiedmann, Cornell University

Dr. John Besser, CDC

Dr. Steve Musser, FDA

Dr. David Goldman, USDA FSIS

Dr. Bill Klimke, NCBI

Dr. Jorgen Schlundt, Global Microbial Identifier

Dr. Jennifer McIntire, United Fresh Produce Association

Dr. Mansour Samadpour, IEH Laboratories and Consulting Group

Ms. Vanessa Coffman, Johns Hopkins University Center for Livable Future

Dr. Tommy Wheeler USDA Agricultural Research Service

Dr. Suelee Robbe-Austerman, USDA Animal Plant Health Inspection Service

Food Safety and Inspection Service:

Roundtable Questions

Suggested Major Themes for Roundtable Discussion:

- **Harborage – what constitutes harborage and how will WGS change our assessment?**
- **Outbreak Investigations – how will this change. How will we detect strains as the same versus different? What are the criteria and rules? How change case-definitions? How important is the epi data and other components of invest?**
- **Under what circumstances would WGS from historical isolates be used by Agencies?**
- **How can agencies enhance the consistency and transparency of WGS data collection and analysis? What are the challenges of communicating decisions based on WGS analysis?**
- **Under what circumstances could WGS be used during routine surveillance, without epi investigation. For example, further characterization, hazard ID, definition of an adulterant. What is the significance of relying on the presence of genes without understanding how or whether they work (i.e. phenotype)?**
- **How can industry take advantage of opportunities to use WGS to improve food safety and quality?**
- **What can industry do to affect the occurrence of specific genotypes (or genomes containing specific genes) identified as being harmful to public health?**