

# A CFSAN Update on Laboratory Operations

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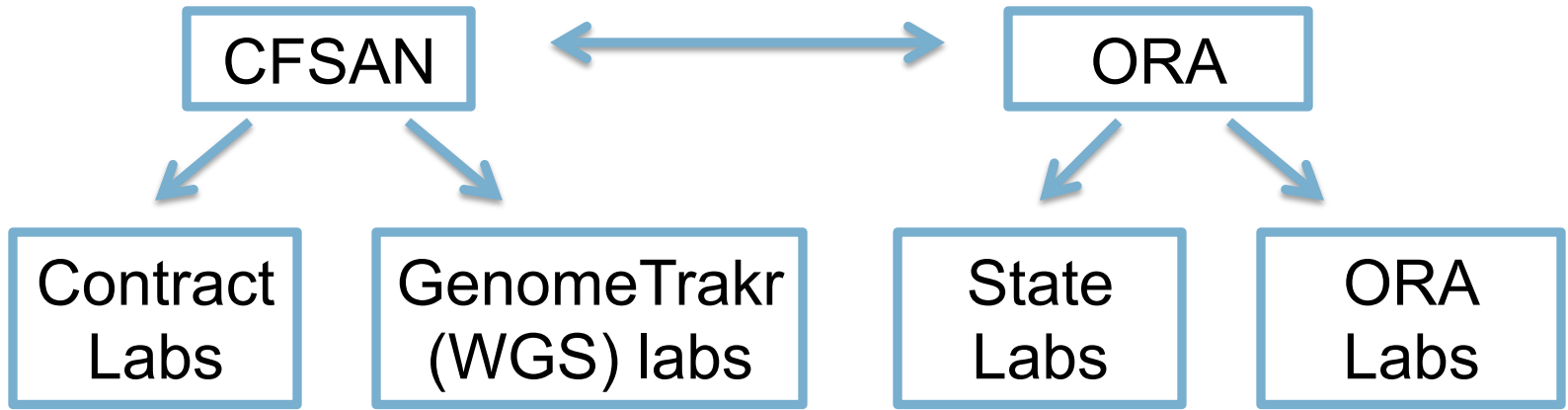
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# Topics

- Sampling strategy and plans
- Contract labs
- New methods
- Whole genome sequencing

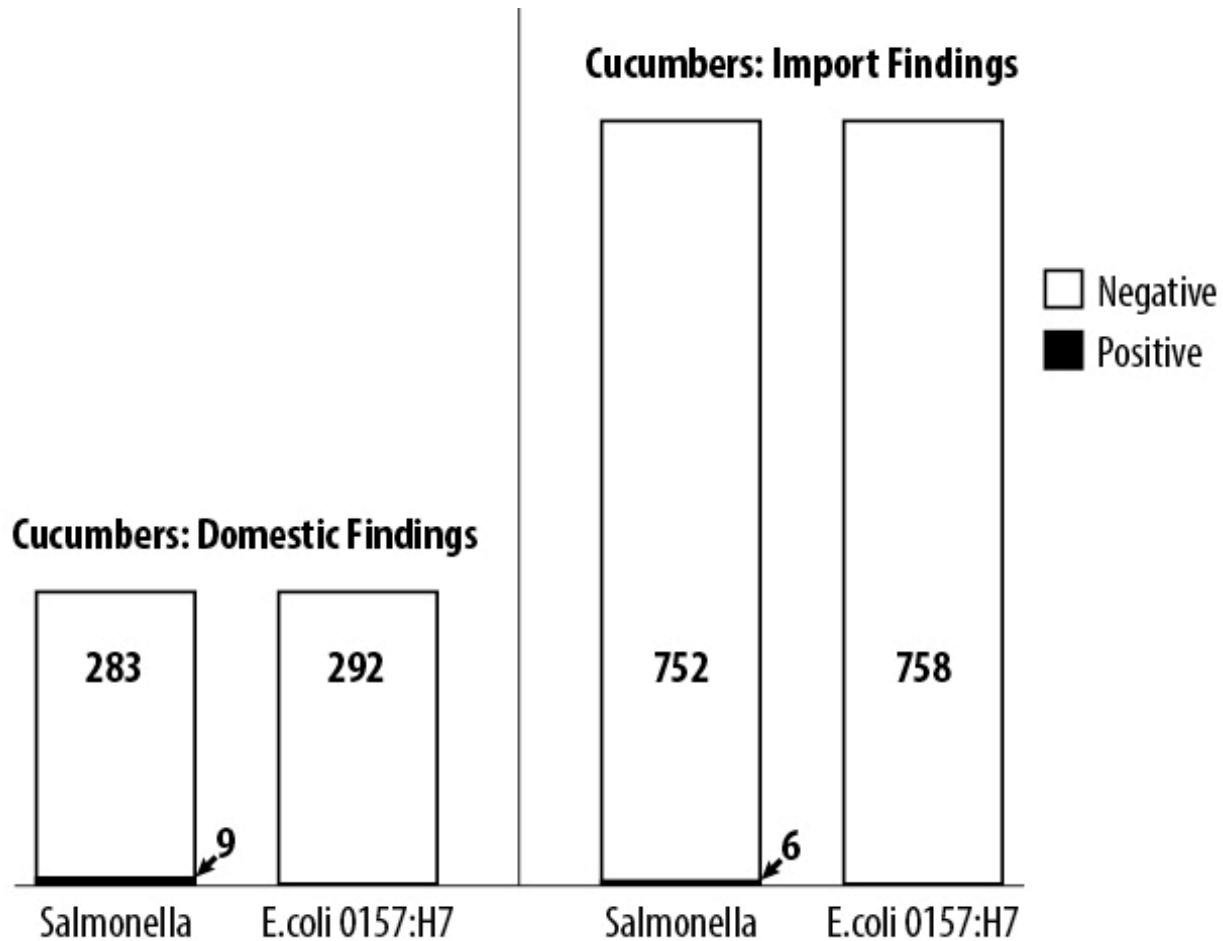
# Organization



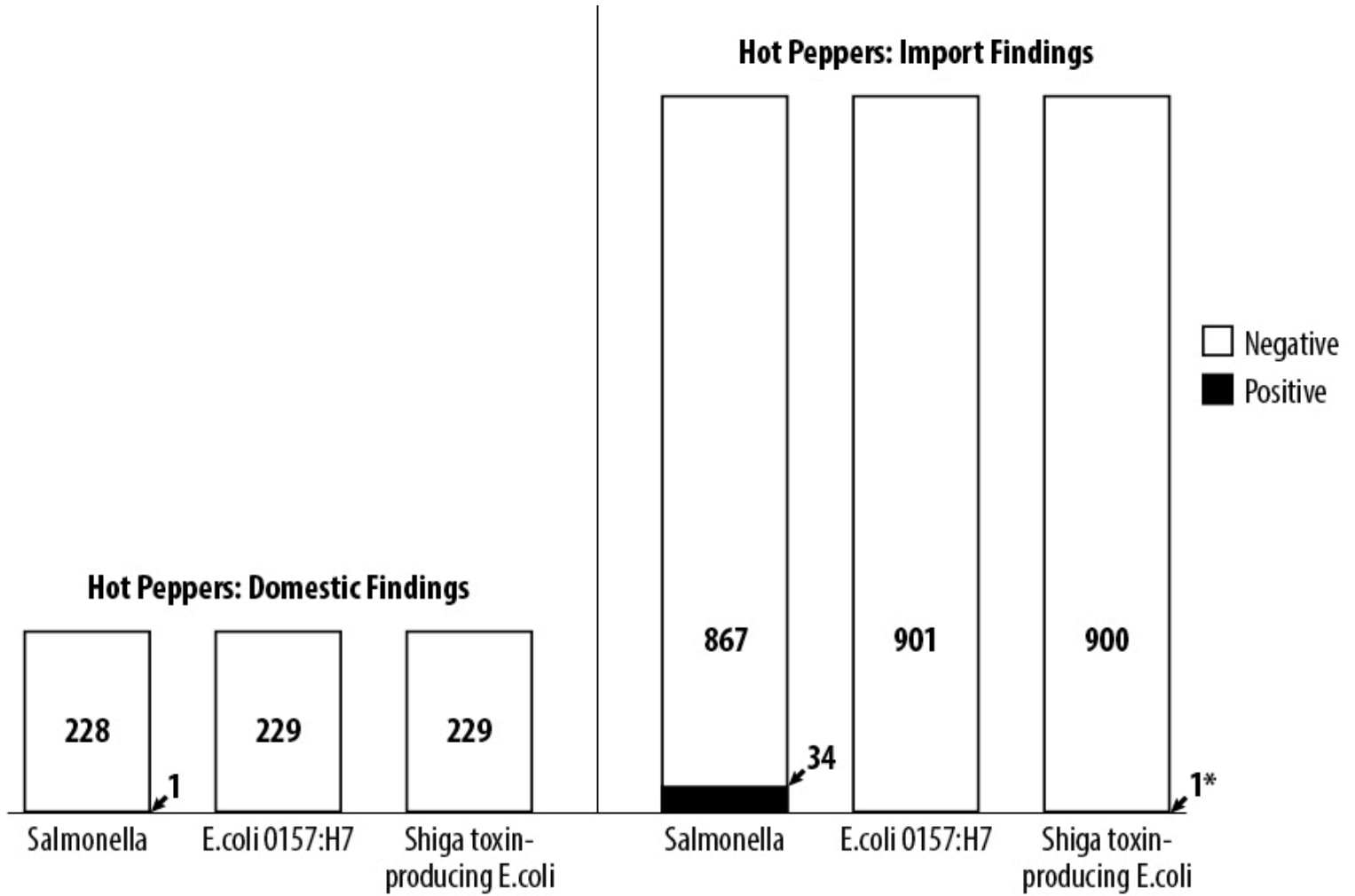
# Focused Sampling and Laboratory Analysis of Foods

- New sampling model based on risk ranking and data gaps
- Statistically relevant number of samples
- Better planning and use of resources
- 2016 – Avocados, cucumbers, hot peppers

# Preliminary results



# Preliminary results



# Contract Laboratory Testing

- Fill large data needs related to retail food samples
- Contract laboratories are ISO 17025 accredited, use CFSAN specified or BAM methods, pass proficiency testing, audited by CFSAN QA unit
- Rapid start and sampling flexibility
- Most cost effective use of resources
- No plans for surveys in FY2017

# Contract Laboratory Testing - Example

- Tree nut survey
  - 600 Raw Walnuts, shelled
  - 600 Raw Pecans, shelled
  - 600 Hazelnuts, shelled and in-shell
  - 600 Raw Cashews, shelled
  - 600 Raw Macadamia Nuts, shelled
  - 600 Raw Pine Nuts, shelled
- Retail samples
- Approximately \$137 sample (shipping, analysis, labor, reporting)



# Contract Laboratory Testing - Example

Nut Type	Conventional	Organic	Total No. of samples tested	No. of samples positive for <i>Salmonella</i>	<i>Salmonella</i> Prevalence (%)
Cashews, shelled	552	181	733	4	0.55 [0.15, 1.40]
Hazelnuts, in-shell	80	0	80	0	0 [0, 4.50]
Hazelnuts, shelled	557	20	577	2	0.35 [0.04, 1.20]
Macadamia nuts, shelled	338	17	355	15	4.20 [2.40, 6.90]
Pecans, shelled	597	26	623	0	0 [0, 0.59]
Pine nuts, shelled	589	41	630	3	0.48 [0.10, 1.40]
Walnuts, shelled	617	41	658	8	1.22 [0.53, 2.40]
Total	3330	326	3656	32	

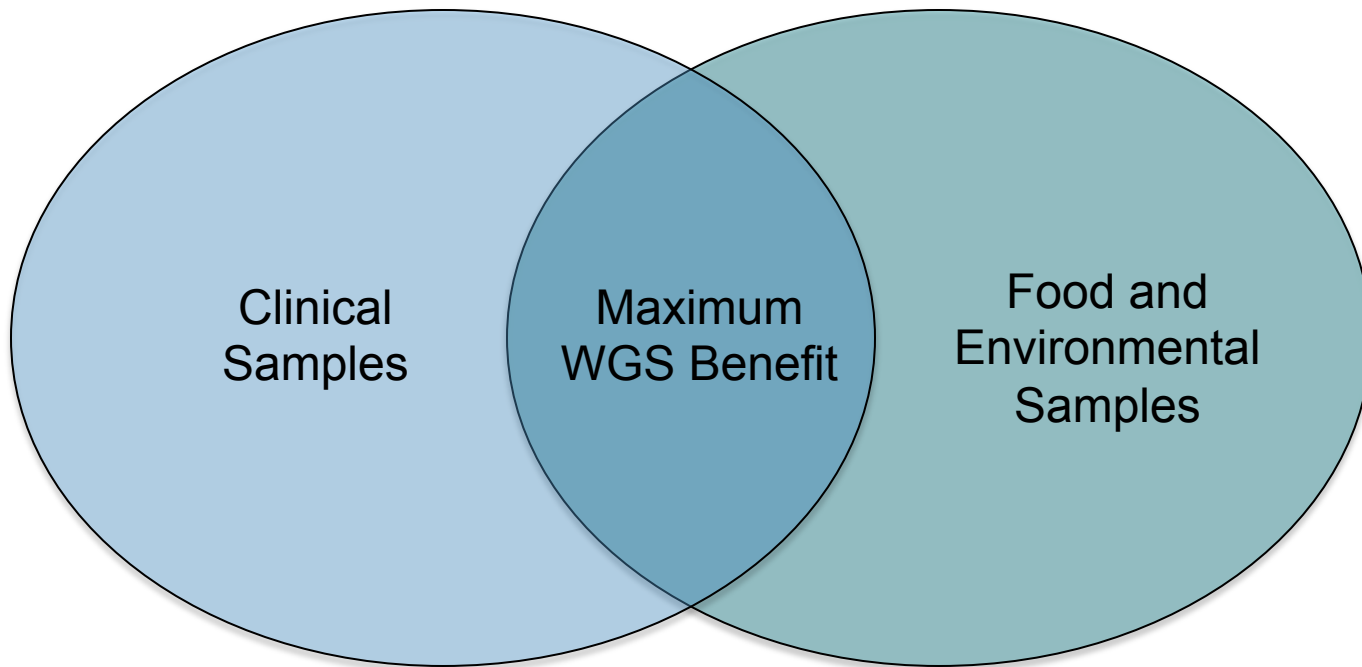
## New method work

- Environmental sampling for *Listeria monocytogenes*
- Improved PCR method for *Cyclospora*
- Continuing development of Hepatitis A methods
- Fully validated qPCR method for *Salmonella*
- New ICP/MS methods for arsenic, lead and cadmium

# What is GenomeTrakr

- A distributed network of laboratories that utilize whole genome sequencing for pathogen identification
- Network was established by FDA in 2011 and is growing rapidly. Now includes CDC, FSIS and dozens of collaborating institutions around the world.
- Open access data curation is provided by the National Center for Biotechnology Information (NCBI)

# Importance of a Balanced Approach



# Benefits of a WGS Approach

- More discriminatory and informative than PFGE
- Clues to geographic origin of pathogen

## **This means:**

- Greater certainty when matching clinical, environmental, and product sample isolates
- Links between illnesses and the potential source of contamination can be made with fewer isolates
- Investigators can be deployed in a more targeted manner, saving resources

## **End Result:**

- Faster identification of the food involved in the outbreak
- Potential to help reduce the number of foodborne illnesses and deaths over the long term both in the U.S. and abroad.

# Current Scope of GenomeTrakr Network

- Network includes labs at FDA, CDC, FSIS, 19 state health and university labs, 1 U.S. hospital lab, and 17 labs located outside the U.S.
  - Contributing labs are on 4 continents and in 10 countries
- The network provides high resolution genomic sequences of food pathogens, ex. *Salmonella*, *Listeria*, STEC's, others. Greater than 100,000 sequences in the database
- Partnered with CDC in 2012 to study all clinical and environmental isolates of *Listeria monocytogenes*

FDA GenomeTrakr website

<http://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/ucm363134.htm>

# Current Status

- WGS is now routine in FDA's outbreak response and compliance/surveillance activities. Internally (across our agency), and in collaboration with FSIS and CDC, WGS has now been deployed and benefitted the traceability of numerous foodborne contamination events.
- WGS can be used to inform traceback investigations and delimit the scope of food contamination events unlike ever before – not just a regulatory tool - numerous offshoot applications exist (i.e., supply chain management, quality assurance, process evaluation, etc.)
- Genome sequences are portable and instantly cross-compatible. One technology approach irrelevant of organism.
- Have to balance the need for increased number of well characterized **environmental** (food, water, facility, etc.) sequences with the need for extensive clinical isolates
- WGS, unlike PFGE, is more than a surveillance tool. It provides information on AMR, Virulence, serotype, and other critical factors in one assay, including historical reference to pathogen emergence.

## Looking ahead

- ❑ Capacity building – hardware, software and people (bioinformatics)
- ❑ Slow movement away from PFGE
- ❑ Bioinformatics - training
  - ❑ Workshops
  - ❑ “Hands on” – JIFSAN
  - ❑ NCBI - <https://www.ncbi.nlm.nih.gov/pathogens/>



# Questions/Discussion